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Attorneys for Petitioner

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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:  
In the Matter of the Arbitration between  
VERIDEX LLC, : Case No. 08 Civ. 3188 (RWS)  
:  
Petitioner, : ECF CASE  
:  
- against - : **NOTICE OF**  
:  
IMMUNICON CORPORATION, : **PETITION TO CONFIRM**  
:  
Respondent. : **ARBITRATION AWARD**  
:  
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**PLEASE TAKE NOTICE** that, upon the annexed Petition of Veridex LLC and the exhibits annexed thereto, and upon the Arbitrator's Award in the arbitration proceeding between Petitioner and Respondent, signed on March 3, 2008 by Arbitrator Roy Reardon, Esq., Petitioner Veridex LLC, by its undersigned attorneys, will move this Court, before a judge of the United States District Court for the Southern District of New York, U.S. Court House, 500 Pearl Street, New York, New York, at a time and date to be determined by the Court, for an order pursuant to the Federal Arbitration Act (9 U.S.C. § 1, *et seq.*):

- (1) Confirming the Arbitrator's Award;
- (2) Directing that judgment be entered thereon; and

(3) Awarding such other and further relief as the Court may deem just and proper.

Dated: New York, New York  
March 31, 2008



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John D. Winter (JW-3252)

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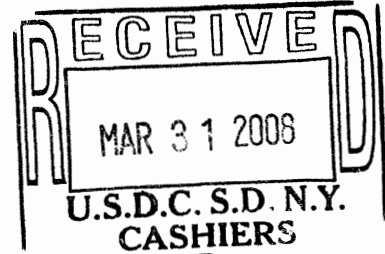
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08 CV 03188

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK



-----X  
In the Matter of the Arbitration between  
VERIDEX LLC,

Petitioner,

- against -

IMMUNICON CORPORATION,

Respondent.  
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**PETITION TO CONFIRM  
ARBITRATION AWARD**

Petitioner Veridex LLC petitions the Court, pursuant to the Federal Arbitration Act, 9 U.S.C. § 1 *et seq.*, for an Order confirming the Arbitrator's Award in the matter of the arbitration between Immunicon Corporation and Veridex LLC, made on March 3, 2008, and directing that judgment be entered accordingly. This petition is made on the following grounds, which Veridex, by and through its undersigned counsel, alleges:

1. Petitioner Veridex is, and at all relevant times has been, a limited liability company duly organized and existing under the laws of New Jersey, with its principal office located in Raritan, Somerset County, New Jersey.

2. On information and belief, Respondent Immunicon is, and at all relevant times has been, a corporation duly organized and existing under the laws of Delaware, with its principal office located in Huntingdon Valley, Montgomery County, Pennsylvania.

3. Ortho-Clinical Diagnostics, Inc. (“OCD”) is, and at all relevant times has been, a New Jersey corporation, with its principal office located in Raritan, Somerset County, New Jersey. OCD is not a party to the present action and was not a party to the arbitration referred to herein.

4. This Court has jurisdiction over this proceeding pursuant to the Federal Arbitration Act, 9 U.S.C. § 9, and pursuant to 28 U.S.C. § 1332(a)(1), in that this action is between citizens of different states, and the amount in controversy, exclusive of interest and costs, exceeds \$75,000.

5. Venue is proper in this judicial district pursuant to 28 U.S.C § 1391(a) and (c), and pursuant to 9 U.S.C. § 9.

6. On August 17, 2000, OCD and Immunicon entered into a written contract titled Development, License and Supply Agreement (the “Agreement”), a copy of which is annexed hereto as Exhibit A, and incorporated by reference herein.

7. The Agreement is a contract evidencing a transaction involving commerce, within the meaning of 9 U.S.C. §§ 1 and 2, in that the stated purpose of the Agreement was “that a full range of cellular human cancer diagnostics [products] . . . be developed and manufactured, in part, by Immunicon and manufactured in part by OCD, and *marketed and distributed worldwide* by OCD.” (Ex. A at § 1 (emphasis added).)

8. Section 14.2 of the Agreement states, in relevant part:

Any controversy or claim arising out of or relating to this Agreement or the validity, inducement, or breach thereof [with one exception not relevant in the present proceeding] shall be settled by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association (“AAA”) then pertaining, except where those rules conflict with this provision, in which case this provision controls.  
***The parties hereby consent to the jurisdiction of the Federal***

***District Court for the Southern District of New York for the enforcement of these provisions and the entry of judgment on any award rendered hereunder . . . .*** [T]he arbitrator shall apply the substantive law of New York (except where the law conflicts [with] this clause) except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act.

(Ex. A at § 14.2 (emphasis added).)

9. In November 2003, Immunicon consented to OCD's assignment to Petitioner Veridex of all rights and interests of OCD under the Agreement, and the assumption by Veridex of all obligations of OCD thereunder.

10. On May 31, 2007, pursuant to the arbitration clause of the Agreement, Immunicon filed its Statement of Claim alleging, *inter alia*, that Veridex had breached its duties under the Agreement, and seeking certain relief against Veridex.

11. On June 22, 2007, pursuant to the arbitration clause of the Agreement, Veridex filed its Answering Statement and Counterclaims responding to Immunicon's allegations, as well as alleging that Immunicon had breached its duties under the Agreement and seeking certain relief against Immunicon.

12. Pursuant to the arbitration clause in the Agreement and the Commercial Arbitration Rules of the American Arbitration Association, the parties validly agreed to the appointment of Roy L. Reardon, Esq. as Arbitrator.

13. Although Section 14.2 of the Agreement calls for arbitration hearings to be held in New Jersey, the parties agreed that without prejudice to Section 14.2 of the Agreement, hearings would be conducted at the New York City offices of Simpson Thacher & Bartlett, LLP, and that all legal rights of the parties shall be the same as if the hearings were physically conducted in New Jersey. The agreement on this point was memorialized in Paragraph 3 of the Arbitrator's Procedural Order No. 1, which was signed by the Arbitrator and

issued on July 17, 2007. A copy of Procedural Order No. 1 is annexed hereto as Exhibit B, and is incorporated by reference herein.

14. The Arbitrator duly conducted a twelve-day hearing commencing on January 7, 2008 and concluding on January 22, 2008. During the hearing, the parties appeared before the Arbitrator and submitted their proof.

15. The Arbitrator studied the facts, circumstances and proofs concerning the controversies submitted to him, and having fully considered all of the evidence and arguments submitted by the parties, the Arbitrator arrived at a Decision and Award and delivered it to the parties on March 3, 2008. A copy of the Decision and Award is annexed hereto as Exhibit C, and is incorporated by reference herein.

16. The Decision and Award was in writing and was duly acknowledged and signed by the Arbitrator. The Decision and Award was made in accordance with the terms and provisions of the Agreement and is in all respects proper.

17. In the Decision and Award, the Arbitrator ordered as follows:

- (a) That Immunicon's claims that Veridex breached its duties under the Agreement be dismissed with prejudice and that Immunicon be awarded no damages;
- (b) That, since there was no fiduciary duty owed by Veridex to Immunicon, Immunicon's claims, based on an alleged breach of fiduciary duty, for forfeiture of Veridex's sales agency commissions and for an award of punitive damages be dismissed with prejudice;
- (c) That Veridex on its counterclaim be awarded damages in the sum of \$304,013.00, with interest calculated in accordance with the law of New York;
- (d) That all other claims asserted by the parties be denied and dismissed with prejudice;
- (e) That no costs or fees, including attorneys' fees, be awarded to either party against the other;

- (f) That the administrative fees and expenses of the arbitration association totaling \$54,560.00 be borne as incurred by the parties;
- (g) That the compensation and expenses of the Arbitrator be borne equally by the parties.

18. Immunicon has not made any payment to Veridex to date.

19. Less than one (1) year has expired since the date of the delivery of the Decision and Award by the Arbitrator to the parties.

20. The Decision and Award has not been vacated, modified, or corrected pursuant to 9 U.S.C. §§ 10 or 11; no application has been made by either party therefor, nor do grounds exist for doing so.

21. Notice of this application has been served upon Immunicon in the manner specified in 9 U.S.C. § 9.

22. Pursuant to New York's Civil Practice Law and Rules § 5001, a party is entitled to interest on a monetary award following a claim for breach of contract. Veridex's counterclaim award is for a breach of contract. See, e.g., Hugh O'Kane Elec. Co., LLC v. MasTec N. Am., Inc., 45 A.D.3d 413, 414, 846 N.Y.S.2d 51, 52 (1st Dep't 2007). The statutory rate of interest under New York law is 9% per annum. See C.P.L.R. §§ 5001, 5004. The interest payable is simple interest, see C.P.L.R. §§ 5001, 5002, which accrues from the date of the Arbitrator's Award. See Bd. of Educ. v. Niagara-Wheatfield Teachers Assoc., 46 N.Y.2d 553, 558, 415 N.Y.S.2d 790, 793 (1979).

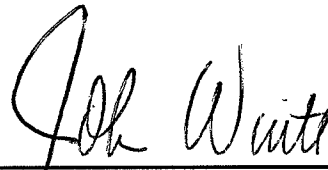
WHEREFORE, Petitioner Veridex requests:

- (1) That an Order of this Court be issued confirming the Decision and Award;
- (2) That, on the basis of the confirmed Decision and Award, the Court enter judgment in conformity therewith, specifying, *inter alia*, that Immunicon is liable to Veridex in the amount of \$304,013.00, plus post-award interest at the rate of 9% (or \$74.96 per day) from

March 3, 2008; and

(3) That Veridex be awarded such other and further relief as the Court deems just and proper.

Dated: New York, New York  
March 31, 2008

A handwritten signature in black ink, appearing to read "John D. Winter", is written over a horizontal line.

John D. Winter (JW-3252)

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Attorneys for Petitioner  
Veridex LLC



60148300  
SEP 08 2000**DEVELOPMENT, LICENSE AND SUPPLY AGREEMENT**

DEVELOPMENT, LICENSE AND SUPPLY AGREEMENT (this "Agreement") dated as of August 17, 2000 by and between IMMUNICON CORPORATION, a Pennsylvania corporation, having its principal office at 3401 Masons Mill Road, Suite 100, Huntingdon Valley, PA 19006 and its subsidiaries (collectively, "Immunicon"), and ORTHO-CLINICAL DIAGNOSTICS, INC., a New York corporation, having its principal office at 1001 US Hwy. #202, Raritan, NJ 08869-0606 ("OCD").

**1. BACKGROUND**

1.0 Immunicon has certain patents and know-how relating to assays useful in the detection of certain human cellular conditions such as the presence of cancerous or pre-cancerous cells in peripheral blood or other body fluids.

1.1 OCD has expertise in the marketing, distribution, and sales of products used in the diagnosis of human disease states and in managing regulatory issues relating to such products.

1.2 Immunicon and OCD desire to collaborate to produce products based upon their respective technologies and businesses with the intent that a full range of cellular human cancer diagnostics shall be developed and manufactured, in part, by Immunicon and manufactured in part by OCD, and marketed and distributed worldwide by OCD.

**2. DEFINITIONS**

"Affiliate" of a party means any entity that directly or indirectly controls, is controlled by or is under common control with such party. "Control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means, in the case of a corporation, the ownership of fifty percent (50%) or more of the outstanding voting securities thereof or, in the case of any other type of entity, an interest that results in the ability to direct or cause the direction of the management and policies of such party or the power to appoint fifty percent (50%) or more of the members of the governing body of the party, or if not meeting the preceding requirement, any company owned or controlled by or owning or controlling a party at the maximum control or ownership right permitted in the country where such party exists.

"Automated Cell Analysis System" means an automated device that is capable of enriching, presenting, characterizing, and counting cells, and providing processed diagnostic information (sufficient for the clinical diagnosis of the presence or absence of Cancer and/or Pre-Cancerous conditions) from cells, all with Clinical Sensitivity meeting the specifications set forth in the Development Plan; wherein such cells are obtained through the use of Cellular Analysis Products.

"Bulk Reagent Cost" means Immunicon's fully-loaded cost per relevant unit of manufacturing Bulk Reagents, determined in accordance with GAAP.

"Calendar Year" means each twelve-month period commencing with January 1 and ending with December 31.

"Cancer" means diseases characterized by uncontrolled growth of abnormal cells that are generally associated with tumor production or tissue invasiveness leading to localized or disseminated tissue pathology.

"Cellular Analysis Product(s)" means products or methods, including without limitation analytical reagents, test kits, consumable products and disposable items, incorporating or utilizing Immunicon Inventions in Cellular Diagnostics.

"Cellular Diagnostics" means: (a) the enrichment or isolation of one or more intact cells from body fluids or lymph nodes (including, without limitation, blood, urine, saliva, semen, stool and stool homogenates, bone marrow, cerebral spinal fluid, gastric juice, nipple aspirates, uterine lavage, cervical lavage, bronchial alveolar lavage, ductal lavage, gastric lavage, and enemas) using magnetic particles in combination with one or more reagents and (b) analyzing, identifying or quantifying cells or one or more cellular components.

"Clinical Sensitivity" means the ability to distinguish between disease states (or precondition for disease states) and non-disease states in a biological sample with a degree of accuracy and precision according to generally acceptable clinical laboratory standards in the United States. Some Clinical Sensitivity criteria will be set forth in the Development Plan. Such criteria apply only to the Cellular Analysis Products or instrumentation to which they refer and only in the context in which they are described.

"Clinical Trial(s)" means human clinical testing meeting the various regulatory requirements and ethical guidelines as may be specified in individual countries where clinical trials of Cellular Analysis Products will be conducted or where such trials will be used to seek approval under Regulatory Authority requirements to market, use and sell Cellular Analysis Products in such country; provided, "Clinical Trials" shall not include post-marketing studies or surveillance.

"Clinical Trial Expenses" means (i) expenses related to Clinical Trial planning, materials, clinical site recruiting, training and participation, monitoring of clinical sites, data analysis and data quality assurance, preparing documents for initial filings for Regulatory Authority submission (including, but not limited to, all fees paid to clinical investigators and patients); (ii) expenses related to planning, managing, carrying out, analyzing and preparing reports of pre-clinical studies necessary to submit as part of initial regulatory marketing applications; (iii) travel expenses related to planning meetings, clinical development or regulatory submissions; and (iv) a reasonable allocation of each of overhead associated with the conduct of such activities and general and administrative expenses. "Clinical Trial Expenses" shall not include any other costs incurred to conduct such trials outside of the Development Plan referred to in Exhibit A. The general and administrative expense component referred to in clause (iv) of this definition shall not exceed twenty-five percent (25%) of the total of all expenses relating to a Clinical Trial.

"Commercial Period" means the period commencing upon the shipment by OCD to a Third Party or an Internal End User of the first Cellular Analysis Product as of the effective date of this Agreement in North America, Japan, or a country that is a member of the European Union, after obtaining Regulatory Approval in such country and ending upon the termination of this Agreement. Sale of a Cellular Analysis Product for research, investigational, or other such uses shall not, by itself, commence the Commercial Period.

"Confidential Information" means (i) any proprietary or confidential information or other material in a tangible form that is marked as "confidential" at the time it is delivered to the receiving party or (ii) proprietary or confidential information disclosed orally that is identified as confidential or proprietary when disclosed and such disclosure of confidential information is confirmed in writing within thirty (30) days by the disclosing party.

"Development Plan" means the written summary of the research and development activities conducted by Immunicon in accordance with the "Development Program" (described in Section 3, below) in order to develop and commercialize Cellular Analysis Products and Automated Cell Analysis Systems. The Development Plan shall be annexed hereto as Exhibit A, as the same may be modified only by the Steering Committee as set forth in Section 3, below.

"Enhancement" means that the product or process under consideration would (i) demonstrate at least a 10% improvement in the recovery of rare cells in a sample of whole blood spiked with less than 0.5 rare cells/ml relative to the then currently available Cellular Analysis Product for determining the quantity of such rare cells (in a similar sample size), or (ii) demonstrate at least a 5% improvement in the clinical sensitivity of rare cell assays (against confirmed positive samples) relative to the then currently available Cellular Analysis Product for determining the presence of such rare cells (including all manual and automated steps such as sample preparation, reagent combination, incubation, and instrument readings), or (iii) reduce the time to produce a result using such assay by at least 25% relative to the then currently available Cellular Analysis Product for determining the presence or quantity of such rare cells (including all manual and automated steps such as sample preparation, reagent combination, incubation, and instrument readings), or (iv) provide a statistical, mathematical, or qualitative parameter for analyzing, identifying or quantifying one or more cellular components wherein such parameter is not readily attainable through the use of the then currently available Cellular Analysis Products or Automated Cell Analysis Systems (e.g., provide a new information channel).

"Enrichment" means the retrieval of sub-populations of nucleated cells from a larger population of nucleated cells by transduction of a force to effect a separation of a substantial majority of the sub-population from the larger population, wherein the sub-population constitutes no more than one one-hundredth of a percent (0.01%) of the total population.

"FDA" means the United States Food and Drug Administration, or any successor body.

"Field" means the human *in vitro* application of Cellular Diagnostics to Cancer and Pre-Cancerous conditions. For the resolution of doubt, the Field shall not include cardiovascular diagnostics and screening, neurological disorder diagnostics, infectious disease diagnostics, hematology, standard blood serum immunoassays for soluble markers and analysis of cells taken by tissue biopsy.

"GAAP" means U.S. generally accepted accounting principles consistently applied.

"Know-How" means any proprietary information including, without limitation, any trade secret, that is useful in any aspect of the development, use, manufacture or sale of Cellular Analysis Products or Automated Cell Analysis Systems and is not publicly known, disclosed or published, including, without limitation, all pre-clinical, clinical, chemical, biochemical, toxicological, analytical, manufacturing, process, formulation and scientific research information, whether or not capable of precise separate description but that alone or when accumulated give to the one acquiring it an ability to study, test, produce, formulate or market Cellular Analysis Products or Automated Cell Analysis Systems which one otherwise would not have known to study, test, produce, formulate or market in the same way.

"Internal End User" means any Affiliate of OCD that is not in the business of reselling Cellular Analysis Products and whose use of such products normally results in such products' consumption.

"Inventions" means the Patents and all inventions (patentable or otherwise), developments, designs, applications, improvements, formulae, concepts, ideas, Know-How, methods or processes, discoveries and techniques necessary or desirable for the development, manufacture, sale or distribution of or otherwise relating to products for the enrichment or isolation of one more intact cells from body fluids and related instrumentation, whether owned as of the date hereof or hereafter acquired or licensed pursuant to the Development Program.

"Marketing Essential Characteristic" means the set of properties, characteristics, and functional requirements that must be incorporated in or displayed by Cellular Analysis Products and Automated Cell Analysis Systems or other instrumentation to make them acceptable to OCD and commercially acceptable in the market in which they are intended to be sold.

"Material Breach" means a failure of a party to perform an express covenant or obligation under this Agreement or a breach of a representation or warranty of a party which failure or breach has had or would reasonably be expected to have a material adverse financial consequence to the non-failing or non-breaching party.

"Microarray Device" means a device embodying an Immunicon Patent that employs ferrofluids to create microarrays for sequential reactions involving nucleic acids as currently claimed (as of the effective date of this Agreement) in U.S. Patent Application 60/175,828 to Gohel, O'Hara, and Barnes.

"Net Sales" means the revenues received by OCD or any of its Affiliates (other than Internal End Users) during a given period from the sale of Cellular Analysis Products to Third Parties and

Internal End Users, less the following amounts: (i) discounts, including cash discounts, or rebates actually allowed or granted, (ii) credits or allowances actually granted upon claims or returns regardless of the party requesting the return, (iii) freight charges paid for delivery and (iv) taxes or other governmental charges levied on or measured by the invoiced amount whether absorbed by the billing or the billed party. In the event that any Cellular Analysis Product is sold in the form of combination products or as a bundle containing one or more other products, Net Sales for such combination products or bundle will be calculated by multiplying actual Net Sales of such combination products by the fraction  $A/(A+B)$  where A is the invoice price of the Cellular Analysis Product if sold separately, and B is the total invoice price of any other product or products in the combination or bundle if sold separately by OCD or any of its Affiliates (or if such other product or products are not sold separately then the standard costs of the Cellular Analysis Products and such other product or products shall be used); provided, however, that in no event shall such fraction be less than 0.85. In the event that any Cellular Analysis Products are sold to Third Parties pursuant to a RAP, OCD shall reasonably determine that portion of the amount charged under the RAP that is attributable to Cellular Analysis Products in accordance with standard OCD accounting procedures, and consistent with generally accepted accounting principles.

"Nonplatform Technology" means technology for use in the Field that does not employ ferrofluids (as defined herein), and is an Enhancement. As used herein, "ferrofluids" means particles having a magnetic core with a mean-longest dimension less than 200 nanometers (nm).

"Patents" means (i) the U.S. and foreign patent applications and patents owned or licensed by Immunicon that are directly related to or have application in Cellular Diagnostics, (ii) U.S. and foreign patent applications and patents owned solely by Immunicon, that claim inventions that are directly related to or have application in Cellular Diagnostics (and which are conceived or reduced to practice as part of the Development Program) and (iii) all divisions, continuations, continuations-in-part, and substitutions thereof; and all extensions, reissues and re-examinations of any of the foregoing; in each case, wherein such patents or applications contain claims that would, but for the licenses granted hereunder, be infringed by OCD's activities in the Field. Exhibit B contains a list of Third Party patents in the Field that are licensed to Immunicon; such Exhibit shall be modified from time to time by Immunicon as such patents expire and licenses are obtained or terminated.

"Pre-Cancerous" means a condition characterized by abnormal cellular changes that show a propensity to become Cancer.

"RAP" means a reagent agreement, reagent rental or similar plan or arrangement wherein Cellular Analysis Products sold by OCD or an Affiliate are increased in price to include an amount to cover the amortized cost of an instrument system, including maintenance costs, or other equipment (amortized over the useful life thereof) supplied to a customer of OCD or an Affiliate under an agreement with the customer to purchase the Cellular Analysis Product(s) at such increased price in order that the customer may have the use of such instrument system and/or other equipment.

"Regulatory Approval" means any approval by a governmental entity to commence commercial sale in any country and any other approvals, clearances, registrations, or permits that may be required to manufacture, market, and sell Cellular Analysis Products, Automated Cell Analysis Systems, or any related components of such Products or instrumentation.



"Regulatory Authority" means all governmental agencies regulating the development, manufacture or sale of Cellular Analysis Products or Automated Cell Analysis Systems in any country or groups of countries.

"Research" means activities conducted to achieve the Milestones and advance the Development Plan or enhance Cellular Analysis Products or Automated Cell Analysis Systems or their use. For the purpose of determining Research funding levels, only the following expenditures shall be included: direct labor and supervision, materials (including those obtained via contract to third parties), prototype production, Clinical Trial Expenses, overhead, and general and administrative expenses (the latter not to exceed twenty percent (20%) of the total of Research expenses).

"Screening Application" means uses or applications of Cellular Analysis Products for the identification from a group of apparently healthy subjects, those people who have Cancer or are at risk of developing Cancer.

"Steering Committee" or "SC" means the Steering Committee described in Section 4 hereof.

"Systems Cost" means Immunicon's standard cost of manufacturing the Automated Cell Analysis System, as determined in accordance with GAAP, based on the number of units forecasted by OCD in accordance with Section 6.7.

"Third Party" means any person or entity other than OCD, Immunicon or their respective Affiliates.

"Works" means the works of authorship, whether or not copyright protected or copyright protectable, relating to products or processes for the enrichment or isolation of one more intact cells from body fluids and related instrumentation, whether owned as of the date hereof or hereafter acquired or licensed pursuant to the Development Program.

### **3. DEVELOPMENT PROGRAM**

3.1 Development Program. Immunicon shall conduct Research under the Development Plan (as set forth in Exhibit A) with the goal of developing Cellular Analysis Products and Automated Cell Analysis Systems for commercial sale. Immunicon shall use its reasonable efforts to conduct the activities for which it is responsible in the Development Program, in accordance with the Development Plan and the provisions of this Agreement, in each case within the time schedule set forth therein and herein. Immunicon will conduct the Development Program in a prudent and skillful manner in accordance in all material respects with the Development Plan then in effect, and in accordance with all applicable Federal, state and local laws, rules, regulations and other requirements (including, without limitation, Good Laboratory Practices, cGMP, QSR, ISO and the regulations of other non-US Regulatory Authorities).

3.2 Program Management. The Steering Committee shall provide oversight and advice for the conduct of the Development Program as follows:

3.2.1 Within thirty (30) days after the date hereof the parties shall form a Steering Committee in accordance with the provisions set forth herein.

3.2.2 The SC shall be composed of three (3) named representatives of OCD, one of whom shall be the senior business representative for the business unit in OCD or its Affiliate in which Cellular Analysis Products are managed, and three (3) named representatives of Immunicon, one of whom shall be the Chief Executive Officer of Immunicon or the senior business representative for the business unit in Immunicon in which Cellular Analysis Products are managed, having a direct reporting relationship to the Chief Executive Officer of Immunicon. Each party may substitute one or more of its representatives, from time to time in its sole discretion, effective upon notice to the other party of such change. OCD shall appoint the chairperson of the SC and so inform Immunicon, including any changes to the designated chairperson.

3.2.3 The purposes of the SC shall be to provide oversight and guidance as to the conduct of the Development Program hereunder and to supervise and coordinate the Clinical Trials and the process of obtaining regulatory approvals of Cellular Analysis Products and Automated Cell Analysis Systems in the various countries. As part of its responsibilities, the SC shall:

- (a) review and approve activities and progress under the Development Plan,
- (b) as necessary, consider and adopt modifications to the Development Plan,
- (c) approve all Clinical Trial protocols,
- (d) approve modifications to plans for conducting Clinical Trials,
- (e) review and evaluate data and conclusions developed from Clinical Trials,
- (f) approve submissions for Regulatory Approval,
- (g) carry out such other activities as the parties may from time to time agree, and
- (h) review and approve terms for any licenses needed under Articles 7.3.1 and 7.3.2.

3.2.4 Unless otherwise agreed, the SC shall meet no less frequently than quarterly. Each party shall be responsible for its own costs incurred in connection with such meetings. The site of the meetings shall alternate between a site chosen by Immunicon and a site chosen by OCD.

3.2.5 Each member of the SC shall have one vote except the chairperson who shall have two votes. Any approval, determination, decision or other action by the SC shall require a majority vote of the total seven votes that may be cast by the members of the SC.

3.2.6 The chairperson of the SC shall prepare and deliver to the other party within thirty (30) calendar days after the date of such meeting minutes of such meeting summarizing the matters reviewed and any actions taken and decisions made at such meetings in form and content reasonably acceptable to the parties.

3.3 Project Representative. OCD and Immunicon each shall appoint a person (a "Project Representative") to oversee the progress of the Development Plan. The Project Representatives shall be the primary contacts between the parties for day-to-day collaboration pursuant to this Agreement. Each party shall notify the other within thirty (30) days after the Effective Date of the appointment of its Project Representatives and shall notify the other party as soon as practicable upon changing this appointment.

3.4 Responsibilities of Immunicon.

3.4.1 Immunicon shall develop the Cellular Analysis Products and Automated Cell Analysis System as described more fully in the Development Plan that is subject to the approval of OCD. Immunicon shall be allowed to utilize its judgment and expertise in conducting the day-to-day activities for the development of Cellular Analysis Products and Automated Cell Analysis Systems but recognizes that OCD wishes to be informed of all key decisions in advance of their execution and be afforded the opportunity to influence the same.

3.4.2 Immunicon shall manage, coordinate, implement and administer the Clinical Trials in accordance with the timeline set forth in the Development Plan. All Clinical Trials of Cellular Analysis Products and Automated Cell Analysis Systems shall be conducted in accordance with all applicable legal and regulatory requirements. Immunicon shall not depart in any material manner from any relevant clinical protocol for a Clinical Trial that is established by the SC, without the prior approval of the SC.

3.4.3 Immunicon will provide all assistance, consultation and advice as necessary or appropriate in connection with the Clinical Trial for the filing of submissions with Regulatory Authorities, and all other aspects of regulatory approval processes. To the extent that the FDA or any other Regulatory Authority requests information with respect to Immunicon in connection with any regulatory filing, Immunicon shall provide such information promptly at no cost to OCD. Immunicon shall use all reasonable efforts to cooperate fully with OCD to comply with and obtain the approval of the Regulatory Authority and all other approvals necessary for OCD to market, sell and distribute products on a worldwide basis. In furtherance, and not in limitation of the foregoing, Immunicon agrees to provide OCD (and any appropriate Regulatory Authority) access to its data, records, facilities, employees and consultants in order to assist in the approval process, subject to appropriate protections for Immunicon's Confidential Information.

3.4.4 At Immunicon's own cost and expense, including, without limitation, the cost and expense of validation, Immunicon will scale-up its production capability to produce Bulk Reagents and Automated Cell Analysis Systems to a level consistent with the demand indicated in the initial Forecast that meets applicable regulatory requirements.

3.5 Funding Obligations.

3.5.1 Immunicon shall allocate a budget covering all Clinical Trial Expenses for Cellular Analysis Products for monitoring and recurrence indications and shall bear up to Five Million dollars (US\$5,000,000), for Clinical Trial Expenses for the first Screening Application set forth in Exhibit C. If Clinical Trial Expenses for such first Screening Application exceed Five Million Dollars (US\$5,000,000) then Immunicon shall not be obligated to pay any such excess amount and OCD shall pay up to Five Million Dollars (US \$5,000,000) of such additional Clinical Trial Expenses. If such additional Clinical Trial Expenses exceed Five Million Dollars (US \$5,000,000)



then the parties shall negotiate in good faith the future terms and conditions under which Clinical Trials for Cellular Analysis Products will be funded.

3.5.2 In all other respects, Immunicon shall be responsible for the funding of its own activities and responsibilities under the Development Plan..

3.5.3 (a) From and after the commencement of the Commercial Period, Immunicon shall invest in Research in each Calendar Year (or for any incomplete Calendar Year, that portion of such Calendar Year) an amount equal to no less than ten percent (10%) of the Net Sales for such Calendar Year (or such portion) until the first Calendar Year during which Net Sales exceed Two Hundred Fifty Million dollars (\$250,000,000). During the Calendar Year in which such Net Sales have been attained and for each Calendar Year thereafter, Immunicon shall invest in Research an amount equal to no less than eight and one-half percent (8.5%) of Net Sales during each such Calendar Year.

(b) In the event that Immunicon shall have not invested in Research up to the amounts required pursuant to Section 3.5.3(a) during any Calendar Year (or portion thereof), Immunicon can cure such failure by investing in Research in the immediately succeeding Calendar Year, in addition to amounts required to be invested pursuant to Section 3.5.3(a), an amount equal to the investment shortfall for such first Calendar Year. Immunicon shall not invoke the provisions of this Section 3.5.3(b) to make up for shortfalls in required Research expenditures for any two consecutive year periods.

(c) From and after the commencement of the Commercial Period, Immunicon shall furnish OCD on a quarterly basis, an accounting of its investments in Research in a format reasonably requested by OCD.

3.5.4 In the event that Immunicon does not meet its Research investment obligations set forth in Section 3.5.3(a) and has not made up any investment shortfalls in accordance with Section 3.5.3(b), then OCD shall have the right, exercisable in its sole and absolute discretion, to fund any or all such activities and responsibilities, in whole or in part, up to the amount of Immunicon's shortfall or adjust Immunicon's share of Net Sales in accordance with Section 6.6.3. If OCD elects to fund such activities, OCD may, in its sole and absolute discretion, elect to recoup any such OCD funding by (a) taking an offset against any fees or portion of Net Sales due Immunicon hereunder or (b) invoicing Immunicon for such funding; such recoupment not to exceed an amount equal to that which Immunicon would otherwise have been obligated to spend for Research under this Agreement. Such offset or invoice shall include recovery of the actual monies expended by OCD, plus the time value of those monies until recovered or repaid, compounded annually at the then current prime interest rate plus three hundred basis points, and the provisions set forth in Section 6.6.3 would not apply with respect to such funding shortfall by Immunicon to the extent of the funding of such shortfall by OCD pursuant to this Section 3.5.4.

### 3.6 Reports and Exchange of Information.

3.6.1 Reports. (a) Immunicon shall report the status of its work in the Development Program, its findings and all results in a manner and at such intervals, as the parties shall reasonably agree but no less frequently than in a written report every calendar quarter and provided to members of the SC no less than one week prior to their scheduled meetings. Each such quarterly written report shall summarize the progress and results during the previous quarter in implementing the Development Plan and achieving its goals and shall provide such other related information as OCD shall reasonably request.

(b) OCD shall report the status of the commercialization of the Cellular Analysis Products and Automated Cell Analysis Systems in a manner and at such intervals, as the parties shall reasonably agree but no less frequently than in a written report every calendar quarter and provided to members of the SC no less than one week prior to their scheduled meetings. Each such quarterly written report shall summarize the progress of OCD's commercialization efforts during the previous quarter in achieving its goals and shall provide such other related information as Immunicon shall reasonably request.

3.6.2 Access to Facilities. Each party agrees to permit personnel of the other party to visit the facilities that are utilized in connection with the production, quality assurance, research and development of Cellular Analysis Products and Automated Cell Analysis Systems, at mutually agreed upon times, during normal business hours to observe the activities being conducted.

3.6.3 Audit Rights. Each party shall have the right, upon reasonable notice to the other and during regular business hours, to inspect and audit the books and records of such party to assure compliance with the provisions of this Agreement including, without limitation, compliance with Sections 3.5.1, 3.5.3, 3.5.4 and 6.2, as well as to determine Immunicon's costs in connection with the Bulk Reagents or the Automated Cell Analysis Products to the extent such costs are passed on to OCD. The parties acknowledge that the provisions of this section granting certain audit rights shall in no way relieve either party of any of its obligations under this Agreement, nor shall such provisions require either party to conduct any such audits.

#### 4.0 PRE-COMMERCIALIZATION ACTIVITIES.

4.1 Marketing Essential Characteristics. OCD shall, in consultation with Immunicon, define the Marketing Essential Characteristics for Cellular Analysis Products, Automated Cell Analysis Systems, and other related instrumentation, components and materials and shall apprise Immunicon of any changes therein. In the event of disagreement regarding Marketing Essential Characteristic definitions, the SC shall decide the matter and such decision shall be final.

4.2 Regulatory Approval Submissions. OCD shall, with the consultation of Immunicon, have the responsibility for submissions in connection with Regulatory Approvals for any Cellular Analysis Product or Automated Cell Analysis System and determine when any regulatory filing for such Cellular Analysis Products and Automated Cell Analysis System should be submitted to a Regulatory Authority. Prior to any submission to any Regulatory Authority, OCD shall consult with, and provide a final draft copy of the proposed submission to Immunicon, which shall, within

twenty (20) days after receipt of the draft, provide any written comments to OCD. OCD shall consider in good faith and consult with Immunicon regarding any such comments, but OCD shall have final decision making authority with respect to all regulatory filings. Necessary filings required for Regulatory Approvals shall be filed within eight (8) months after completion of the Clinical Trials.

**4.3 Supplemental Submissions.** OCD shall consult with Immunicon concerning all supplemental or additional regulatory and other governmental submissions related to Cellular Analysis Products, Automated Cell Analysis Systems, and other related instrumentation, components and materials and provide Immunicon with access to such submissions prior to filing the same.

**4.4 Ownership of Approvals.** All documents filed with Regulatory Authorities shall be submitted in the name of OCD or one of its Affiliates and OCD shall own all such Regulatory Approvals unless otherwise required by applicable law.

**4.5 Filling and Packaging.** At OCD's own cost and expense, including, without limitation, the cost and expense of validation, OCD shall make ready a facility (either owned by OCD or an Affiliate thereof or by a Third Party) for filling and packaging Bulk Reagents into Cellular Analysis Products consistent with the initial forecast and shall make ready a facility (either owned by OCD or an Affiliate thereof or by a Third Party) for the repair of Automated Cellular Analysis Systems, in each case that meets applicable regulatory requirements.

## **5. Milestones and Milestone Payments**

**5.1 Initial Payment.** In partial consideration of the rights and licenses granted hereunder, within three (3) business days after the Effective Date of this Agreement, OCD shall pay to Immunicon the nonrefundable amount of One Million Five Hundred Thousand Dollars (US \$1,500,000) which shall not be creditable against the purchase of products by OCD hereunder. Immunicon shall incorporate \$1.0 million of this sum in its budget for Research in Screening Applications and shall dedicate it to those activities. Further, the parties acknowledge that this Agreement shall not be effective until Johnson & Johnson Development Corporation ("JJDC") and Immunicon shall have completed JJDC's purchase of Immunicon's Series E Preferred Stock for an aggregate purchase price of \$5,000,003.22.

**5.2 Milestone Payments.** In further consideration of the rights and licenses granted hereunder, OCD shall pay Immunicon nonrefundable payments within thirty (30) days after the date that any of the milestones shall have been achieved according to the standards and specifications set forth in Exhibits C and D and as set forth below, which payments shall not be creditable against the purchase of products by OCD hereunder and which payments shall be made irrespective of whether or not milestone completion occurs before the completion dates indicated (subject, however, to the adjustments set forth in Section 5.4).

**5.2.1** Five Hundred Thousand Dollars (US\$500,000) upon successful completion of a pre-Clinical Trial demonstrating readiness to develop and execute a Clinical Trial protocol for breast Cancer therapy monitoring using a Cellular Analysis Product. This milestone shall be complete when the results of such pre-Clinical Trial provide data sufficient to indicate that

Clinical Trials for such a Cellular Analysis Product can be successfully conducted (as determined by the SC). The completion date for this milestone is December 31, 2001.

5.2.2 One Million Dollars (US\$1,000,000) upon the successful demonstration by Immunicon that a Cellular Analysis Product produced by Immunicon is suitable for a breast Cancer Screening Application. This milestone shall be complete when such Cellular Analysis Product demonstrates requisite recovery of cells, sensitivity and specificity relative to mammography and tissue biopsy, the ability to distinguish signal from noise, and sample stability and preparation requirements, all according to the standards and under the conditions set forth in Exhibits C and D of this Agreement (as determined by the SC). The completion date for this milestone is July 1, 2002.

5.2.3 Five Hundred Thousand Dollars (US\$500,000) upon the successful demonstration by Immunicon of its ability to automate Cancer Cellular Diagnostics. This milestone shall be complete when a commercially feasible analytical module of the Automated Cell Analysis System has been developed that is capable of being manufactured in commercial quantities and such Cell Analysis System demonstrates Clinical Sensitivity for detecting the presence and type, and/or the extent or stage of breast Cancer in a breast Cancer monitoring application as determined by the SC. The completion date for this milestone is July 1, 2003.

5.2.4 Five Hundred Thousand Dollars (US\$500,000) upon the demonstration of an automated sample preparation system. This milestone shall be complete when a commercially feasible automated sample preparation system has been developed that is capable of being manufactured in commercial quantities and such system can be used as part of an Automated Cell Analysis System, in each case as determined by the SC. The completion date for this milestone is July 1, 2003.

5.2.5 One Million Dollars (US\$1,000,000) upon the first submission by OCD of a request for Regulatory Approval by the FDA for a Cellular Analysis Product that includes an indication for breast Cancer therapy monitoring according to a submission and claims that have been approved by the SC. The completion date for this milestone is April 1, 2003.

5.2.6 One Million Five Hundred Thousand Dollars (US\$1,500,000) upon receipt by OCD of the approval sought by the submission referred to in Section 5.2.5. This milestone shall be complete when the FDA has granted Regulatory Approval to OCD for such Cellular Analysis Product, and Immunicon has produced three consecutive lots of approved Cellular Analysis Product manufactured under GMP (or the then current FDA standard), and Immunicon has demonstrated the ability to produce an inventory to satisfy quantities of such Cellular Analysis Products necessary to satisfy forecasted quantities demanded, in each case as determined by the SC. The completion date for this milestone is December 31, 2003.

5.2.7 One Million Dollars (US\$1,000,000) upon the submission by OCD of a request for Regulatory Approval to the FDA for a Cellular Analysis Product that includes an indication for a colorectal Cancer therapy monitoring that can be conducted on an Automated Cell Analysis System. This milestone shall be complete when such request is submitted by OCD in a form and according to claims that have been approved by the SC. The completion date for this milestone is April 1, 2004.

5.2.8 One Million Dollars (US\$1,000,000) upon the submission by OCD of a request for Regulatory Approval for a Cellular Analysis Product for a breast Cancer recurrence monitoring indication that can be conducted on an Automated Cell Analysis System. This milestone shall be complete when such request is submitted by OCD to the FDA for a Cellular Analysis Product that includes an indication for breast Cancer recurrence monitoring that can be used in an Automated Cell Analysis System and wherein such request is in a form and according to claims that have been approved by the SC. The completion date for this milestone is December 31, 2004.

5.2.9 Two Million Dollars (US\$2,000,000) upon the granting of FDA approval to OCD for marketing a Cellular Analysis Product in the United States for a breast Cancer Screening Application for women twenty five (25) years of age and older. This milestone shall be complete when such approval is obtained for a Cellular Analysis Product having the characteristics described in Section 5.2.2 above used with samples processed with an automated sample handling system and analyzed with an Automated Cell Analysis System. The completion date for this milestone is July 1, 2007.

5.3 Stacking of Milestone Payments. In the event that more than four (4) of the milestone payments under Section 5.2 become due in any one Calendar Year, Immunicon shall permit OCD, upon receipt of its written request, to defer any additional milestone payments otherwise due into the next succeeding Calendar Year, provided that such deferred payments shall become due and payable within thirty (30) days following the commencement of the succeeding Calendar Year.

5.4 Delay of Milestones. Both parties understand that delays in achieving milestones may have serious adverse economic consequences. Accordingly, in the event the actual date of occurrence of the events corresponding to the foregoing exceeds the target completion dates specified in Section 5.2, then, for a period of ten years from the date of commencement of the Commercial Period, Immunicon's share of Net Sales shall be reduced by a factor of 0.5% of such share (e.g., from 31% to 30.5%) for Net Sales of the Cellular Analysis Product to which the missed milestone relates. However, in no event shall the total of the amount by which Immunicon's proportionate share of Net Sales be reduced by more than a factor of 0.5% of Immunicon's share of the total of Net Sales of all Cellular Analysis Products. For purposes of this Section 5.4, the target completion date set forth in Sections 5.2.5, 5.2.7 or 5.2.8, shall be moved back one day for each day beyond six (6) months that it takes OCD to submit the regulatory filing referred to in such section provided that such 6-month period shall not commence until such time as OCD shall have received all information from Immunicon that OCD, in its reasonable judgment, determines to be necessary in order to make such filing.

5.5 Post Milestone Activities. Upon completion of the Milestones, Immunicon shall direct its Research first to the development of a Cellular Analysis Product for multi-Cancer screening as defined by the SC and then to other products as the SC shall determine

## 6. COMMERCIAL ACTIVITIES.



6.1 Reagent Manufacturing and Supply Arrangement. Except as expressly provided elsewhere in this Agreement, Immunicon shall exclusively manufacture (or cause to be manufactured) and supply OCD with OCD's requirements of Cellular Analysis Products and OCD shall source such requirements exclusively from Immunicon, as follows:

6.1.1 Bulk Reagents. (a) Prior to the commencement of the Commercial Period, Immunicon shall manufacture and supply OCD with OCD's requirements for the bulk reagent component (the "Bulk Reagents") of the Cellular Analysis Products for OCD to create finished Cellular Analysis Products, in amounts reasonably requested by OCD from time to time in connection with OCD's validation of finishing and packaging facilities, marketing activities as well the performance by OCD of its obligations hereunder with respect to making appropriate regulatory filings. The Bulk Reagents shall meet the specifications therefor as set forth in Schedule 6.1.1 hereto, as amended from time to time by mutual agreement of the parties (the "Reagent Specifications").

(b) From and after the commencement of the Commercial Period, Immunicon shall manufacture and supply OCD with OCD's requirements for Bulk Reagents for OCD to create finished Cellular Analysis Products, as ordered by OCD and meeting the Reagent Specifications, subject to the limitations set forth in Section 6.7.

6.1.2 Transfer Pricing. OCD shall pay to Immunicon an amount equal to the Bulk Reagent Cost for that amount of Bulk Reagent shipped to OCD that meets the Reagent Specifications within thirty (30) days after receipt by OCD of the invoice therefor except that Immunicon will ship to OCD reasonable amounts (not to exceed, in the aggregate, \$50,000 worth of Bulk Reagent at Bulk Reagent Cost) of Bulk Reagent at no charge in order for OCD to make ready and validate its facility for filling and packaging pursuant to Section 4.5.

6.2 Sharing of Net Sales. Within thirty (30) days after the end of each calendar quarter commencing with the first commercial sale of Cellular Analysis Products OCD shall remit to Immunicon thirty-one percent (31%) of Net Sales recorded by OCD during such calendar quarter, (in order to compensate Immunicon for (a) Bulk Reagents supplied to OCD in accordance with Section 6.4, (b) for Immunicon's investment in Research in accordance with Section 3.5.3 and (c) the balance as a royalty under Patents and Know How), which amount is subject to adjustment as set forth in Sections 5.4 and 6.6 of this Agreement, less the Bulk Reagent Cost for that amount of Bulk Reagents that was incorporated in and/or used to make the Cellular Analysis Products that generated such Net Sales. The parties acknowledge and agree that as of the date hereof it is not possible to determine the amount of Bulk Reagents that are necessary to produce each unit of Cellular Analysis Product taking into account such things as manufacturing yield and related matters. Therefore, the parties will use reasonable efforts to reach agreement on the amount of Bulk Reagents that will be required to produce a unit of Cellular Analysis Product in order to determine the amount by which Immunicon's portion of Net Sales shall be reduced in accordance with the last phrase of the first sentence of this section. For the avoidance of doubt, in no case will Immunicon be entitled to payments from OCD in excess of thirty-one percent (31%) of Net Sales for any Calendar Year.

### 6.3 Arrangements for Uses of Cellular Analysis Products for Analyzing Genetic Information.

(a) OCD, by itself or with a Third Party may develop and/or produce products, articles of manufacture, compositions, methods, or instrumentation, for clinical or diagnostic testing, or testing for determinations regarding therapy, based on genetic information (i.e., derived from RNA or DNA analysis) wherein cellular components so analyzed are obtained by the use of Cellular Analysis Products. Section 6.2 shall not apply to the sale of such products, articles, compositions, or instrumentation by OCD or its Affiliates. In such a case, unless subject to the terms of Section 6.3(b) or 6.3(c) below, OCD or such Affiliate shall pay to Immunicon an amount equal to (i) Immunicon's fully allocated cost of the Cellular Analysis Products supplied by Immunicon, multiplied by a factor of 1.40, (ii) for any Automated Cell Analysis System supplied, the terms set forth in Section 6.4 shall apply, and (iii) a royalty in an amount equal to 6.50% of Net Sales (one-half of which is attributable to each of Patents and Know How), which royalty would be subject to adjustment as set forth in Section 6.6.4.

(b). In the event that Immunicon develops an analyzer (other than a Microarray Device) that provides diagnostic information based on genetic information (i.e., derived from RNA or DNA analysis) for use in the Field that was not developed as part of the Development Program or funded in whole under the terms of this Agreement, and OCD or an Affiliate of OCD sells or has sold such instruments for use with Cellular Analysis Products then the Net Sales from the sale of Cellular Analysis Products utilizing such analyzer will be shared in accordance with the terms set forth in Section 6.2 with the following modifications:

- (i) Royalties or other fees required to be paid for the use of Third Party technology that is paid to Third Parties by OCD shall be deducted from Net Sales; and
- (ii) In the event that such analyzer is developed with or incorporates know-how from OCD or an Affiliate of OCD that relates directly to genetic information then OCD or its Affiliate shall be due a know how royalty of 10% of Net Sales, such sum to be deducted from amounts otherwise owed to Immunicon by OCD;

provided, however, that in no event shall Immunicon receive, pursuant to this clause (b), an amount less than Immunicon's fully allocated cost of the Cellular Analysis Products and such analyzer supplied by Immunicon pursuant to this clause (b), multiplied by a factor of 1.40 and 10% of Net Sales (sixty percent of which is attributable to Patents and forty percent of which is attributable to Know How). Further, in the event that the parties each desire to participate in the funding and/or development of such analyzer then the parties will negotiate in good faith the terms of the development and funding of such new system and, if the parties are able to reach agreement thereon, such arrangement will be set forth in a separate agreement from this Agreement which arrangement would contain financial terms and conditions (i) not less favorable to OCD than the terms relating to the sharing of Net Sales for Cellular Analysis Products as set forth in Section 6.2 and (ii) not less favorable to Immunicon than the terms set forth elsewhere in this Section 6.3(b). If, after such negotiations, the parties are unable to agree on such terms and if OCD obtains a firm commitment by a Third Party for the development of such systems that is 20% less than the cost estimated by Immunicon (based on substantially similar terms) then OCD shall be free to contract with such Third Party. In such event, either (a) the terms of Section 6.3(a) shall apply, or (b) Immunicon shall manage the efforts of such Third Party, in which case the terms of such arrangement shall be as set forth in a separate agreement from this Agreement. OCD shall not request any negotiation under this Section 6.3(c) for at least one Calendar Year from the effective date of this Agreement.

(c). In the event that OCD or an Affiliate of OCD desires to sell an Immunicon Microarray Device for use with Cellular Analysis Products then the parties will negotiate in good faith the terms of the development and supply of such new system and, if the parties are able to reach agreement thereon, such arrangement will be set forth in a separate agreement from this Agreement which arrangement would contain financial terms and conditions (i) not less favorable to OCD than the terms relating to the sharing of Net Sales for Cellular Analysis Products as set forth in Section 6.2 and (ii) not less favorable to Immunicon than the terms set forth in Section 6.3(b). If, after such negotiations, the parties are unable to agree on such terms and if OCD obtains a firm commitment by a Third Party for the development of such systems that is 20% less than the cost estimated by Immunicon (based on substantially similar terms) then OCD shall be free to contract with such Third Party. In such event, either (a) the terms of Section 6.3(a) shall apply, or (b) Immunicon shall manage the efforts of such Third Party, in which case the terms of such arrangement shall be as set forth in a separate agreement from this Agreement. OCD shall not request any negotiation under this Section 6.3(c) for at least one Calendar Year from the effective date of this Agreement.

#### 6.4 Arrangements Relating to Automated Cell Analysis Systems.

6.4.1 Sales Agency Arrangement. Unless and until OCD, pursuant to Section 6.4.2, exercises its right to convert the sales agency arrangement set forth in this Section 6.4.1 into a distributorship arrangement, the following terms and conditions shall govern the marketing and selling of the Automated Cell Analysis Systems:

(a) Appointment as Sales Agent. Immunicon hereby appoints OCD and its Affiliates as Immunicon's exclusive sales, invoicing and collecting agent as well as the exclusive instrument and technical service provider for Automated Cell Analysis Systems. As such agent, each of OCD and its Affiliates will contract on behalf of Immunicon for (i) the sale, lease or other transfer of the Automated Cell Analysis System within the Field and (ii) invoice and collect monies due from customers for their purchase, lease or other method of acquisition thereof.

(b) Authority of each of OCD and its Affiliates as Immunicon's Agent. (a) Each of OCD and any of its Affiliates that act as a sales agent under this Agreement will assess the creditworthiness of potential customers, and if determined to be acceptable using OCD's internal standards of commercial judgment, OCD or such Affiliate shall accept orders and send such accepted orders to Immunicon who will ship the Automated Cell Analysis Systems directly to the customers. Immunicon will retain title to the Automated Cell Analysis Systems and will have the risk of loss with respect thereto until title passes to customers (at which time the customers shall have risk of loss) in accordance with the terms of the customer agreements, the form of which shall be determined by OCD and reasonably agreed to by Immunicon. Immunicon will notify OCD when Automated Cell Analysis Systems have been shipped to a customer and thereafter OCD will bill the customer in OCD's usual manner. OCD invoices and purchase orders will be used and name and trademarks designated by OCD will be clearly associated with the product code and quantity. OCD shall have no authority (i) to assume or create any obligation of any kind, expressed or implied, on behalf of Immunicon, except as expressly set forth in this Agreement or (ii) to make any representation, warranty or agreement in the name or on behalf of Immunicon with respect to any matter



except for those expressly made by Immunicon in this Agreement or otherwise agreed to in writing by Immunicon.

(c) Use of Subagents. Notwithstanding anything to the contrary in this Agreement, OCD and its Affiliates may appoint as subagents, and delegate its duties as sales, invoicing and collecting agent (as set forth in this Section 6.4.1) to any other Person subject to the prior consent of Immunicon, such consent not to be unreasonably withheld. No such delegation shall relieve OCD of its obligations under this Agreement.

(d) Sales and Training Costs. OCD shall be responsible for all expenses which it may incur in carrying out its sales and training responsibilities hereunder including, without limitation, all travel expenses (including meals and lodging) and those expenses associated with the training of its employees and officers at the facilities of OCD and elsewhere related to the Automated Cell Analysis Systems. Immunicon shall be responsible for providing appropriate training to OCD to enable OCD to train customers of the Automated Cell Analysis Systems.

(e) Promotional Efforts; Materials; Claims; Trademarks. OCD shall be responsible for all expenses which it may incur in marketing, selling and promoting the Automated Cell Analysis System, to include but not limited to, (i) selling aids, (ii) promotional materials and (iii) distribution related items. In any event, Immunicon shall have the right to review materials relating to OCD's promotional efforts as Immunicon's sales agent with respect to Automated Cell Analysis Systems.

(f) Demonstration and Other Units; System Specifications; Validation; Testing; Labelling. Prior to the first commercial sale, lease or other transfer of an Automated Cell Analysis System, Immunicon shall manufacture or cause to be manufactured the Automated Cell Analysis Systems in amounts reasonably requested by OCD from time to time in connection with OCD's marketing and other obligations hereunder (provided that Immunicon shall not be required to ship more than fifty (50) demonstration units to OCD) as well the performance by OCD of its obligations hereunder with respect to making appropriate regulatory filings. Units needed by OCD for testing of Cellular Analysis Products, training of marketing and service personnel (subject to the 50 unit limit), regulatory approvals and other reasonable non-commercial purposes will be transferred to OCD at Immunicon's Systems Cost, F.O.B. OCD's designated location within the continental United States. The Automated Cell Analysis Systems supplied under this Agreement to OCD or to customers shall meet the specifications therefor as agreed to by the parties and as may be amended from time to time by the parties (the "System Specifications"). Immunicon, on behalf of OCD, shall perform all software development and validation of the Automated Cell Analysis Systems and all testing and quality assurance release functions for the Automated Cell Analysis Systems generally as well as the software contained therein; provided that the quality assurance release criteria shall be subject to the mutual agreement of the parties and the application thereof shall be subject to the audit and inspection rights of OCD. The Automated Cell Analysis System shall be in OCD's labeling or as otherwise determined by OCD.

(g) Sales Agency Commission; RAP. (i) Subject to clause (ii) of this paragraph (g), in consideration of its sales agency and billing and collecting activities in connection with the Automated Cell Analysis System OCD will receive a sales agency commission in an amount equal to fifteen percent (15%) of the amount invoiced to each customer to whom an Automated Cell

Analysis System is sold, leased or otherwise transferred. Within thirty days after the end of each calendar month OCD will remit an amount equal to the sums billed by OCD to customers of the Automated Cell Analysis System during such calendar month, less the amount of OCD's sales agency commissions due OCD under this clause (g)(i) based on amounts billed by OCD during such month. Any bad debt recognized by OCD during any month will be deducted by OCD from monies due to Immunicon at the end of such month.

(ii) In the event that Automated Cell Analysis Systems are placed with customers pursuant to a RAP, OCD rather than the customer will purchase such Automated Cell Analysis Systems from Immunicon at 50% of Systems Cost and Immunicon will ship such Automated Cell Analysis System directly to the customer and Immunicon will send the invoice therefor to OCD and such invoice will be due and payable by OCD within 30 days after OCD's receipt thereof and no commission shall be payable in connection with any such RAP arrangement.

(h) Pricing to Customers. OCD will set the pricing for sales of the Automated Cell Analysis Systems to customers (such price, the "Customer Price"). In the event that the Customer Price is less than System Cost plus 27.5% in connection with the sale of any Automated Cell Analysis System, then such shortfall shall first be applied to any commission that is due OCD in connection with such sale and any remaining shortfall shall be remitted by OCD to Immunicon with any other calendar quarterly payments made by OCD to Immunicon in accordance with Section 6.4.1(g). The parties shall use all commercially reasonable efforts to minimize the Systems Cost.

(i) Warranty and Service: Customer Support. Immunicon shall provide to those customers who purchase, lease or otherwise acquire an Automated Cell Analysis System with a warranty covering parts and labor for, or replacement of, the Automated Cell Analysis System which warranty shall run for a period of twelve (12) months after the date such system is installed at an end user site (such period, the "Initial Warranty Period") which means that in the event that such system fails to operate in accordance with the System Specifications during the Initial Warranty Period Immunicon shall be responsible for paying cost of repairs and/or replacement of parts or the entirety of the system. In the event that during the Initial Warranty Period for any Automated Cell Analysis System a customer utilizing such system reports a problem with such system to OCD, OCD shall repair such system. OCD shall notify Immunicon of such problem within three (3) days after OCD shall have been notified of such problem. If a repetitive failure persists in any account, Immunicon may elect after receipt of such notice from OCD (by sending written notice to OCD of its intention to do so) and at Immunicon's own cost and expense, to send out its own technician to the customer site to evaluate and remedy such problem, otherwise OCD will evaluate and remedy such problem on its own. In the event that after the expiration of the Initial Warranty Period with respect to any Automated Cell Analysis System, more than three (3) service calls in any Calendar Year are required to be made with respect to such system (excluding any such calls for the purpose of preventive maintenance), then the parties will share the costs equally with respect to those service calls for such system in excess of 3 during such Calendar Year except that for any such Calendar Year that falls within the second twelve-month period after the first commercial sale of Cellular Analysis Products the parties will share such expenses for such systems in excess of four (4) (rather than 3) service calls during such Calendar Year. OCD will provide integrated systems technical support to the customer.

(j) Forecasting: Supply Process. In order to expedite the supply process, OCD as Immunicon's sales agent, will be responsible for forecasting Automated Cell Analysis System requirements on which manufacturing plans will be based in accordance with the provisions set forth in Section 6.7.

6.4.2 Conversion to Distributorship: Terms of Distribution Arrangement. At any time during the initial term of this Agreement, OCD may upon twelve (12) months written notice to Immunicon cause the parties to restructure the sales agency arrangement set forth in Section 6.4.1 into a distributorship arrangement with respect to the Automated Cell Analysis Systems, in which case the following terms and conditions (and not those set forth in Section 6.4.1) shall apply:

Except as expressly provided elsewhere in this Agreement, Immunicon shall exclusively manufacture (or cause to be manufactured) and supply OCD with OCD's requirements of Automated Cell Analysis Systems and OCD shall source such requirements exclusively from Immunicon, as follows:

(a) Prior to the first commercial sale, lease or other transfer of an Automated Cell Analysis System, Immunicon shall manufacture or cause to be manufactured the Automated Cell Analysis Systems in amounts reasonably requested by OCD from time to time in connection with OCD's marketing and other obligations hereunder (provided that Immunicon shall not be required to ship more than fifty (50) demonstration units to OCD) as well the performance by OCD of its obligations hereunder with respect to making appropriate regulatory filings. Units needed by OCD for testing of Cellular Analysis Products, training of marketing and service personnel (subject to the 50 unit limit), regulatory approvals and other reasonable non-commercial purposes will be transferred to OCD at Immunicon's Systems Cost, F.O.B. OCD's designated location within the continental United States. The Automated Cell Analysis Systems supplied under this Agreement shall meet the System Specifications. Immunicon shall perform all software development and validation of the Automated Cell Analysis Systems and OCD will perform all testing and quality assurance release functions for the Automated Cell Analysis Systems generally as well as the software contained therein.

(b) From and after the commencement of the Commercial Period, Immunicon shall manufacture and supply OCD with its requirements for Automated Cell Analysis Systems as forecasted and ordered by OCD meeting the System Specifications, subject to the limitations set forth in Section 6.7.

(c) Upon Immunicon's receipt of a purchase order from OCD, Immunicon shall ship unit(s) of the Automated Cell Analysis Systems to the customers or other entities designated by OCD in such purchase orders. Upon such shipment of units Immunicon shall issue an invoice to OCD in an amount per unit (consisting of one sample processor and one analytical module) shipped equal to Systems Cost plus 27.5% (the "Initial Transfer Price"), which invoice shall be due and payable by OCD within forty-five days after OCD's receipt thereof; provided, however, that if OCD's net proceeds from the sale of such unit, less fifteen percent (15%), is greater than the Initial Transfer Price then OCD shall remit the overage to Immunicon within thirty (30) days after the end of each calendar quarter. Where Automated Cell Analysis Systems are placed with customers pursuant to a RAP, Immunicon will adjust the invoice to OCD to 50% of Systems Cost and such invoice will be

due and payable by OCD within 30 days after OCD's receipt thereof. The parties shall use all commercially reasonable efforts to minimize the Systems Cost.

(d) The terms set forth in Section 6.4.1(i) shall apply to the distributorship arrangement except that the warranty during the Initial Warranty Period shall run to OCD rather than the customer.

#### 6.5 Bonus Payments.

6.5.1 Within forty-five (45) days after the end of the first Calendar Year during which Net Sales exceed Two Hundred Fifty Million Dollars (\$250,000,000), OCD shall make a one-time payment to Immunicon in the amount of Two Million Dollars (\$2,000,000).

6.5.2 Within forty-five (45) days after the end of the first Calendar Year during which Net Sales exceed Five Hundred Million Dollars (\$500,000,000), OCD shall make an additional one-time payment to Immunicon in the amount of Three Million Dollars (\$3,000,000).

6.5.3 Within forty-five (45) days after the end of the first Calendar Year during which Net Sales exceed One Billion Dollars (\$1,000,000,000), OCD shall make an additional one time payment to Immunicon in the amount of Five Million Dollars (\$5,000,000).

#### 6.6 Adjustments to the Sharing of Net Sales.

6.6.1 If at any time during the term of this Agreement, Immunicon shall stop supplying OCD with Cellular Analysis Products and/or Automated Cell Analysis Systems pursuant to Section 13.2, Immunicon's share of Net Sales shall be ten percent (10%).

6.6.2 If at any time during the term of this Agreement any Cellular Analysis Products or the Automated Cell Analysis System would not, but for the license granted to OCD hereunder, infringe a valid, unexpired claim of any patent granted to Immunicon in any country then Immunicon's share of Net Sales arising from the sale of products in such country shall be that percentage of Net Sales otherwise due to Immunicon pursuant to this Agreement, less six percent (6%).

6.6.3 If at any time during the term of this Agreement Immunicon ceases its Research activities relating to the Development Plan or otherwise fails to fully fund the amount of Research that Immunicon is expressly obligated to invest in Research pursuant to Section 3.5.3, then Immunicon's share of Net Sales during any Calendar Year shall be reduced by an amount equal to the amount that Immunicon is expressly obligated to invest in Research pursuant to Section 3.5.3 during such Calendar Year, less the amount invested in Research by Immunicon during such Calendar Year (except that to the extent that OCD elects to fund all or a portion of such then OCD shall recoup such funding in accordance with the provisions set forth in Section 3.5.4).

6.6.4 In the event that there is substantial infringement by a Third Party of any Patent having claims to a Cellular Analysis Product or Automated Cell Analysis System (i.e., such third party is making, using, selling, or importing a competitive product that embodies an invention claimed in a Patent, and sales of such other product in the country of the Patent in question are at least ten percent (10%) of OCD's sales of such product in such country), OCD shall notify Immunicon in writing to that effect. If, prior to the expiration of ninety (90) days from the date of said notice, Immunicon obtains a discontinuance of such infringement or brings suit against the Third Party infringer and diligently prosecutes such suit, then OCD's obligation to pay Immunicon shall continue unchanged. If, after the expiration of said ninety (90) days from the date of said notice, Immunicon has not obtained a discontinuance of such infringement, or brought suit against the Third Party infringer or if Immunicon fails to diligently prosecute such suit, then the Immunicon's share of Net Sales in the affected jurisdiction shall be that percentage of Net Sales otherwise due to Immunicon, less three percent (3%).

6.6.5 Automated Cell Analysis Systems, shall be limited to accepting and utilizing Cellular Analysis Products sold by OCD.

#### 6.7 Forecasts and Ordering

6.7.1 Strategic Forecast. On or prior to May 1, 2001, OCD shall provide Immunicon with a non-binding, five-year strategic forecast of the worldwide demand for Cellular Analysis Products and Automated Cell Analysis Systems which shall represent OCD's good faith estimate of such demand based on information then available to OCD. The purpose of the strategic forecast is to enable Immunicon to determine in its own reasonable judgment its manufacturing capacity strategy.

6.7.2 Forecasts. At the beginning of each calendar quarter after the calendar quarter during which the first forecast is provided in accordance with the immediately succeeding sentence, OCD



shall provide Immunicon with a written forecast (the "Forecast") of OCD's expected requirements for Bulk Reagents and Automated Cell Analysis Systems during the four calendar quarters (the first calendar quarter of which shall be the first full calendar quarter after the calendar quarter during which such Forecast is provided by OCD), the first quarter of which shall be binding upon both parties with respect to Bulk Reagents only and the remaining three calendar quarters shall be provided for planning purposes only and shall not be binding upon either party. On or prior to the second full calendar quarter prior to the anticipated first commercial sale of Cellular Analysis Products OCD shall provide Immunicon with a Forecast covering the first four calendar quarters commencing with the first calendar quarter during which it is anticipated the first commercial sale of Cellular Analysis Products shall take place, provided that with respect to this first Forecast no portion of that Forecast shall be binding on either party.

6.7.3 Limits on Product Orders. Commencing with the first full calendar quarter after Net Sales shall exceed \$50,000,000 for any twelve-month period, Immunicon shall use commercially reasonable efforts but shall otherwise not be required to fill any orders of OCD placed in accordance with the provisions set forth in Section 6.7 to the extent such orders (a) for any Calendar Year, exceed 200% of the amount of product so ordered by OCD during the immediately preceding Calendar Year to the extent Immunicon was required to fill the product so ordered by OCD during such preceding Calendar Year or (b) for any calendar quarter, exceed 120% of the amount of product so ordered by OCD during the immediately preceding calendar quarter to the extent Immunicon was required to fill the product so ordered by OCD during such preceding calendar quarter.

6.7.4 Orders. OCD shall place any binding orders for Bulk Reagents, and for Automated Cell Analysis Systems, if the arrangement relating thereto shall have been converted to a distributorship pursuant to Section 6.4.2, by written or electronic purchase order (or by any other means agreed to by the parties) to Immunicon, which shall be placed at least ninety (90) days prior to the desired date of delivery. Immunicon shall be obligated to accept and fill orders that exceed the Forecast by up to 20%.

6.7.5 Conflicts. To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern.

6.7.6 Annual Forecast. During the Commercial Period, OCD shall develop and provide to Immunicon an annual forecast (the "Annual Forecast") for North America, Europe and/or Japan (the "Major Regions") 90 days prior to the commencement of the Calendar Year (commencing with the first full Calendar Year during which Cellular Analysis Products and the Automated Cell Analysis System is approved for sale in such Major Region) which forecast will set forth the number of units and sales of such products, by product code, that are forecasted to be sold or recorded during such Calendar Year.

## 6.8 Delivery and Inventory

6.8.1 Delivery. All charges for packing, hauling, storage, bar coding, and transportation to point of delivery are included in the transfer prices unless otherwise agreed to by the parties. All shipments must be accompanied by a packing slip that describes the articles, states the purchase order number and shows the shipment's destination. Immunicon agrees to promptly forward the original bill of lading or other shipping receipt for each shipment in accordance with OCD's instructions. Immunicon further agrees to promptly render, after delivery of goods or performance of services, correct and complete invoices to OCD, and to accept payment by check or at OCD's discretion, other cash equivalent (including electronic transfer of funds).

6.8.2 Shipment. The risk of loss with respect to Bulk Reagents and Automated Cell Analysis Systems, if the arrangement relating thereto shall have been converted to a distributorship pursuant to Section 6.4.2, shall remain with Immunicon until the same is delivered to OCD at its facilities or such other location as shall be designated by OCD as a point of delivery. Immunicon will pack all Bulk Reagents and Automated Cell Analysis Systems ordered hereunder in a manner suitable for shipment and sufficient to withstand the effects of shipping, including handling during loading and unloading.

6.8.3 Inventory. Immunicon will maintain inventory of Bulk Reagents and Automated Cell Analysis Systems on a first-in, first-out basis. Immunicon and OCD agree to cooperate to improve the process for ordering Bulk Reagents and Automated Cell Analysis Systems with the mutual objectives of expediting the supply process and reducing inventory costs.

#### 6.9 Improvement and Changes to the Bulk Reagents and Automated Cell Analysis Systems

In no event shall any change, improvement or modification to any Bulk Reagents or Automated Cell Analysis Systems (or any change or modification to the specifications therefor) be implemented or made without the prior written approval of OCD. If the parties agree on any such change, improvement or modification, they shall modify the Reagent or System Specifications to reflect the same. Immunicon further agrees that no significant changes or modifications to the method or process of manufacture or production of any Bulk Reagents or Automated Cell Analysis Systems shall be made without prior written notification to and approval of OCD. In the event of any change, OCD shall establish an appropriate qualification protocol, and OCD and Immunicon shall determine an appropriate inventory level for the pre-change Bulk Reagents or Automated Cell Analysis Systems, as the case may be, in order to cover on-going requirements during the qualification process.

#### 6.10 QUALITY/DEFECTIVE PRODUCT/INSPECTIONS/TESTING

6.10.1 Inspections. (a) OCD shall have the right, upon reasonable notice to Immunicon and during regular business hours, to inspect and audit the facilities being used by Immunicon (or any third party) for production and storage of Bulk Reagents or instrument systems to assure compliance by Immunicon (and its suppliers) with GMP and applicable FDA and other rules and regulations and with other provisions of this Agreement. Immunicon shall within thirty days remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies can not reasonably be remedied within such thirty day period, present to OCD a written plan to remedy such deficiencies as soon as possible; and the failure by Immunicon to remedy or cause the

remedy of any such deficiencies within such thirty day period or to present such a plan within such thirty day period and then use its commercially reasonable efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a Material Breach of this Agreement. Immunicon acknowledges that the provisions of this Section granting OCD certain audit rights shall in no way relieve Immunicon of any of its obligations under this Agreement, nor shall such provisions require OCD to conduct any such audits.

(b) Immunicon shall have the right, upon reasonable notice to OCD and during regular business hours, to inspect and audit the facilities being used by OCD for finishing and filling the Cellular Analysis Products and the storage of such Products to assure compliance by OCD with GMP and applicable FDA and other rules and regulations and with other provisions of this Agreement. OCD shall within thirty days remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies can not reasonably be remedied within such thirty day period, present to Immunicon a written plan to remedy such deficiencies as soon as possible; and the failure by OCD to remedy or cause the remedy of any such deficiencies within such thirty day period or to present such a plan within such thirty day period and then use its commercially reasonable efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a Material Breach of this Agreement. OCD acknowledges that the provisions of this section granting Immunicon certain audit rights shall in no way relieve OCD of any of its obligations under this Agreement, nor shall such provisions require Immunicon to conduct any such audits.

6.10.2 Quality. Immunicon warrants that any Bulk Reagents or Automated Cell Analysis Systems sold to OCD or any customer hereunder shall comply in all respects with the Reagent Specifications or the System Specifications, as the case may be, therefor and shall be free from defects in design, material and workmanship.

6.10.3 Disposition of Defective Product. Without prejudice to any other remedy which OCD may have, Immunicon shall replace at its own cost and expense, including reimbursement of freight and disposition costs incurred by OCD, any Bulk Reagent or Automated Cell Analysis Systems that fails to comply with the Reagent Specifications or the System Specifications, as the case may be, or has any such defects. OCD shall notify Immunicon of the existence and nature of any non-compliance or defect and Immunicon shall have a reasonable opportunity, not to exceed ten (10) days from receipt of notification, to inspect such defective Bulk Reagents or Automated Cell Analysis Systems, as the case may be, and provide OCD with detailed written instructions to return or dispose of such defective Bulk Reagents or Automated Cell Analysis Systems, as the case may be. OCD shall have no obligation to pay for any Bulk Reagents or Automated Cell Analysis Systems, as the case may be, that is subject to such a claim of non-compliance or defect. If Immunicon fails to so inspect and instruct OCD as to the disposition of such defective Bulk Reagents or Automated Cell Analysis Systems, as the case may be, OCD may dispose of such defective Bulk Reagents or Automated Cell Analysis Systems as it sees fit and Immunicon shall promptly (1) reimburse OCD for all direct, out-of-pocket costs incurred by OCD in such disposition, and (2) replace such defective Bulk Reagents or Automated Cell Analysis Systems at its own cost and expense.



**6.10.4 Independent Testing.** If, after Immunicon's inspections of such Bulk Reagents or Automated Cell Analysis Systems, as the case may be, the parties disagree as to whether the Bulk Reagents or Automated Cell Analysis Systems conform to the applicable Specifications or whether the Bulk Reagents or Automated Cell Analysis Systems has such a defect, either party may deliver the item to a validated, independent third-party laboratory, mutually and reasonably acceptable to both parties, for analytical testing to confirm such item's conformance to the Reagent or System Specifications or the presence or absence of defects. All costs associated with such third-party testing shall be at OCD's expense unless the tested item is deemed by such third-party to be defective or not in compliance with the applicable Specifications, in which case all such costs, including reimbursement of freight and disposition costs, shall be promptly paid by Immunicon. No inspection or testing of or payment for Bulk Reagents or Automated Cell Analysis Systems, as the case may be, by OCD or any third-party agent of OCD shall constitute acceptance by OCD thereof, nor shall any such inspection or testing be in lieu or substitution of any obligation of Immunicon for testing, inspection and quality control as provided in the applicable Specifications or under applicable local, state, or federal laws, rules, regulations, standards, codes or statutes.

**6.10.5 Corrective Action.** In the event any governmental agency having jurisdiction shall request or order, or if OCD shall determine to undertake, any corrective action with respect to any Cellular Analysis Product or Automated Cell Analysis Systems, as the case may be, including any recall, corrective action or market action, and the cause or basis of such recall or action is attributable to any cause, fact of condition other than a breach by OCD of any of its warranties, guarantees, representations, obligations or covenants contained herein, then Immunicon shall be liable, and shall reimburse OCD for the reasonable costs of such action including the cost of any Cellular Analysis Product or Automated Cell Analysis Systems, as the case may be, that is so recalled whether or not any such specific unit of Bulk Reagents or Automated Cell Analysis Systems shall be established to be in breach of any warranty by Immunicon hereunder. If any such corrective action is taken as result of a breach by OCD of any of its warranties, guarantees, representations, obligations or covenants contained herein, OCD shall reimburse Immunicon for its costs.

#### **6.11 SUPPLY ASSURANCES: FAILURE TO SUPPLY: FORCE MAJEURE: SECOND MANUFACTURING SITE**

**6.11.1 Supply Assurances: Failure to Supply.** The parties recognize that the availability of adequate quantities of Bulk Reagents, Cellular Analysis Products and Automated Cell Analysis Systems consistent with the Forecast is essential for the commercial success of Cellular Analysis Products. The parties therefore agree as follows:

(a) Immunicon shall maintain an inventory of Bulk Reagents and Automated Cell Analysis Systems and OCD shall maintain an inventory of Cellular Analysis Products, each sufficient to satisfy the Forecast for such products for at least three (3) months based on OCD's requirements for the prior Calendar Year (or, during the first Calendar Year after the first commercial sale, the first three (3) months set forth in the Forecast).

(b) If Immunicon, for more than thirty (30) days during the term of this Agreement, for reason other than Material Breach of this Agreement by OCD, is unable to meet the firm portion

of OCD's Forecast (subject to the limitations set forth in Section 6.7.3) which supply shortfall accounts for at least 5% of Net Sales that would be generated from the sale of Cellular Analysis Products over such period during which such shortfall has occurred, then upon ninety (90) days written notice from OCD, OCD shall be free to utilize its License to make or have made Bulk Reagents, or Automated Cell Analysis Systems, as the case may be, until such time as Immunicon fully resumes its supply obligations hereunder; provided that OCD shall have no obligation to purchase Bulk Reagents or Automated Cell Analysis Systems, as the case may be, from Immunicon until any reasonable contractual obligations that OCD has assumed in connection with producing the same or obtaining such substitute source of supply shall have terminated except that if Immunicon has fully resumed manufacturing and for twelve (12) months after such resumption Immunicon has been able to sustain manufacturing at levels that Immunicon reasonably believes would satisfy OCD's product requirements under this Agreement based on demand forecasts then OCD would be required to source its product requirements hereunder exclusively from Immunicon commencing with the first anniversary date of such resumption. Immunicon shall use its best efforts to give OCD access to any licenses that it possesses that, absent which, Cellular Analysis Products or Automated Cell Analysis Systems, as the case may be, would infringe a valid claim, technical and proprietary materials, information and techniques necessary or helpful for OCD to produce or arrange an alternative supplier of Bulk Reagents or Automated Cell Analysis Systems, as the case may be, and to provide advice and consultation in connection therewith. Payment to Immunicon during such period will be decremented by 10 percentage points.

**6.11.2 Force Majeure Events.** If either party is prevented from performing any of its obligations hereunder due to any cause which is beyond the non-performing party's reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (a "Force Majeure Event"), such non-performing party shall not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. Such non-performance will be excused for three months or as long as such event shall be continuing (whichever occurs sooner), provided that the non-performing party gives immediate written notice to the other party of the Force Majeure Event. Such non-performing party shall exercise all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable.

**6.11.3 Second Manufacturing Site.** Immunicon agrees to develop a manufacturing contingency plan acceptable to the SC which will consist of either a second-site manufacturing capability or the qualification of a contract manufacturer which plan shall be developed when determined by the SC. The second site or alternate manufacturer shall be sufficiently remote from Immunicon's existing manufacturing facility so as to minimize the likelihood that both facilities would be destroyed or substantially damaged by a common casualty or disaster. Immunicon shall periodically review with OCD the status and future plans regarding second-site manufacturing. Should Immunicon fail to establish a second site or alternate manufacture in accordance with the timeline set forth in the plan, OCD may, at its sole discretion, establish such site and therein manufacture up to 50% of the volume of Bulk Reagents.

## **6.12 LABELING; ARTWORK; PROPRIETARY RIGHTS**

OCD shall have the right to determine the appearance and text of any labeling and packaging used in connection with any Cellular Analysis Product or Automated Cell Analysis Systems, as the case may be, or any component thereof. Except as otherwise expressly provided herein, Immunicon acknowledges that OCD is the exclusive owner of and has all rights to the trademarks, tradenames, copyrights, slogans, artwork and all other intellectual property that appear on or are otherwise used in connection with the sale, marketing and distribution of the any Cellular Analysis Product and the Automated Cell Analysis Systems, as the case may be, or any component thereof.

#### 6.13 BULK REAGENT AND AUTOMATED CELL ANALYSIS SYSTEMS REPRESENTATIONS AND WARRANTIES

Immunicon represents and warrants to OCD that all Bulk Reagents or Automated Cell Analysis Systems, as the case may be, supplied in connection with this Agreement shall be of merchantable quality, free from defects in material and workmanship and shall be manufactured and provided in accordance and conformity with the applicable Specifications and in compliance with this Agreement. Immunicon represents and warrants that it shall comply with all present and future statutes, laws, ordinances and regulations relating to the manufacture and supply of Bulk Reagents being provided hereunder, including, without limitation, those enforced by the United States Food and Drug Administration (including compliance with good manufacturing practices) and International Standards Organization Rules 9000 et seq.

#### 6.14 COMPLIANCE

The Parties agree to comply with the applicable provisions of any Federal or state law and all executive orders, rules and regulations issued thereunder, whether now or hereafter in force, including Executive Order 11246, as amended, Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.1 of Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap; Section 60.250.4 of Chapter 60 of 41 Code of Federal Regulations, as amended, providing for the employment of disabled veterans and veterans of the Vietnam era; Chapter 1 of Title 48 of the Code of Federal Regulations, as Amended, Federal Acquisition Regulations; Sections 6, 7 and 12 of the Fair Labor Standards Act, as amended, and the regulations and orders of the United States Department of Labor promulgated in connection therewith; and any provisions, representations or agreements required thereby to be included in this Agreement are hereby incorporated by reference. If any Bulk Reagents or Automated Cell Analysis Systems, as the case may be, are ordered or contracted for sale pursuant to Section 6.4.1 by OCD under U.S. government contracts, Immunicon agrees that all applicable federal statutes and regulations applying to OCD as a contractor are accepted and binding upon Immunicon insofar as Immunicon may be deemed a subcontractor and OCD shall give Immunicon prior notice of its entering into any such government contracts and the terms thereof to enable Immunicon to take such steps to comply with such statutes and regulations.

#### 6.15 TAXES

Any Tax required to be withheld under US law on amounts payable under this Agreement shall promptly be paid by OCD or its Affiliate on behalf of Immunicon or its Affiliate to the appropriate governmental authority, and OCD or its Affiliate shall furnish Immunicon or its Affiliate with proof of payment of such tax, together with official or other appropriate evidence issued by the appropriate governmental authority, sufficient to enable Immunicon or its Affiliate to support a claim for income tax credit in respect of any sum so withheld. Any such tax required to be withheld shall be an expense of and borne by Immunicon or its Affiliate.

## **7. INTELLECTUAL PROPERTY**

**7.1 Ownership of Inventions.** All right, title, and interest in any Inventions or Works existing as of the date of this Agreement, will be retained by the current holder. All right, title, and interest in Inventions or Works made solely by employees of Immunicon during the term of this Agreement shall be owned by Immunicon. All right, title, and interest in Inventions or Works made solely by OCD employees during the term of this Agreement shall be owned by OCD. Title to all Inventions or Works made jointly by employees of Immunicon, on the one hand, and employees of OCD, on the other hand, shall be jointly owned by Immunicon and OCD as tenants in common.

### **7.2 License Grant.**

**7.2.1** Immunicon grants to OCD, a world-wide exclusive right under Immunicon Inventions to make, have made, use, sell, and have sold Cellular Analysis Products and Automated Cell Analysis Systems within the Field subject to the limitations set forth elsewhere in this Agreement. OCD shall have the right to sublicense the aforementioned rights to only those Third Parties approved in writing by Immunicon; such approval shall not be unreasonably denied. For the resolution of doubt, the grant of this license shall have no effect on Immunicon's rights outside the Field.

**7.2.2** Immunicon grants to OCD, a world-wide sole right to reproduce, prepare derivative works, distribute, perform, and display Immunicon Works in the Field; in each case such rights shall include the right of OCD to have such act conducted by a Third Party for the benefit of OCD. Selection of such Third Parties shall be subject to the written approval of Immunicon which shall not be unreasonably denied. For the resolution of doubt, the grant of this license shall have no effect on Immunicon's rights outside the Field.

### **7.3 Third Party Licenses.**

**7.3.1** Immunicon shall be responsible for and shall bear all costs, fees, royalties, or other payments associated with obtaining any license from a Third Party that upon reasonable advice of Immunicon's counsel are required to develop or commercialize Cellular Analysis Products and Automated Cell Analysis Systems, conduct activities under the Development Plan, achieve the Milestones or otherwise perform under this Agreement. Such costs, fees, royalties, or other payments may be applied to Immunicon's Research funding obligations hereunder.

7.3.2 In the event that OCD desires the modification of a Cellular Analysis Product, Automated Cell Analysis System, any related components or materials, or any process relating to them wherein such modification requires a license from a Third Party and such modification would result in an Enhancement of such products in effect on the date of the first commercial sale of the product in question, then OCD shall pay sixty nine percent (69%) of the costs, fees, royalties, or other payments associated with obtaining any such license and Immunicon shall pay thirty one percent (31%) of such costs, fees, royalties, or other payments. Any license cost, fee, royalty, or payment made by Immunicon pursuant to this Section 7.3.2 shall not be applied to Immunicon's Research funding obligation hereunder.

7.3.3 In the event that either party desires the use or incorporation of any Third Party Nonplatform Technology, the following procedure shall be used:

a. the party having such desire shall present the relevant information to the other party including data reasonably acceptable to one skilled in Field that indicates that such Nonplatform Technology provides an Enhancement and is technically and commercially feasible,

b. the party to whom the information is presented in (a) above shall accept or decline inclusion of the Nonplatform Technology, if such party accepts inclusion of the Nonplatform Technology then OCD shall pay sixty nine percent (69%) of all costs, fees, royalties, or other payments associated with obtaining any such Nonplatform Technology and Immunicon shall pay thirty one percent (31%) of such costs, fees, royalties, or other payments. The distribution of revenues for any products incorporating such Nonplatform Technology shall be as set forth in Section 6 (subject to the adjustments set forth in such section).

c. in the event that the party to whom the information is presented in (a) above declines inclusion of the Nonplatform Technology, then the other party shall again offer the inclusion of such technology to the declining party when clinical utility for products embodying such technology has been demonstrated and available data is sufficient to indicate that Clinical Trials for products embodying such technology can be successfully conducted. If the party to whom the information is presented under this section then accepts inclusion of such technology then the party that initially declined inclusion of the Nonplatform Technology shall pay to the other party a sum equal to the amount they would otherwise have paid according to (b) above plus the same proportion of any additional costs, fees, royalties, or other payments associated with obtaining such Nonplatform Technology. The distribution of revenues for any products incorporating such Nonplatform Technology shall be as set forth in Section 6 (subject to the adjustments set forth in such section).

d. in the event that the party to whom the information is presented in (c) above declines the inclusion of such technology then:

i. if such declining party is OCD:

1. Immunicon shall be free to explore the commercialization of such Nonplatform Technology alone or with any Third Party,

2. OCD shall have the right to terminate Immunicon's Research obligations under this Agreement and reduce any sums thereafter payable to Immunicon under Section 6 above by the amount set forth in Section 6.6.3,

3. Immunicon shall continue to supply OCD with Bulk Reagents for Cellular Analysis Products and Automated Cell Analysis Systems subject to a right in OCD to terminate



such supply on three year's written notice; thereafter any sums payable to Immunicon under Section 6 above shall be reduced by ten percent (10%) based on Net Sales.

4. The covenants of Section 15.7 shall thereafter have no effect.

ii. if such declining party is Immunicon:

1. Immunicon shall have the right to negotiate with any Third Party the right to make, have made, use, sell, and have sold Cellular Analysis Products and Automated Cell Analysis Systems,

2. Immunicon shall have the right to declare the license set forth in section 7.2 nonexclusive upon the first commercial sale of a product embodying such Nonplatform Technology,

3. Immunicon shall continue to supply OCD with Bulk Reagents for Cellular Analysis Products and Automated Cell Analysis Systems subject to a right in Immunicon to terminate such supply on three year's written notice

4. The covenants of Section 15.7 shall thereafter be have no effect

7.3.4 In the event that either party desires the use or incorporation of any Enrichment Technology for human in-vitro cellular diagnostics for Cancer other than Cellular Diagnostics (that is, non-magnetic technologies; referred to hereinafter as "Enrichment Technology" for the purposes of this Section 7.3.4), the following procedure shall be used:

a. the party having such desire shall present the relevant information to the other party including data reasonably acceptable to one skilled in Field that indicates that such Enrichment Technology provides an Enhancement and is technically and commercially feasible,

b. the party to whom the information is presented in (a) above shall accept or decline inclusion of such Enrichment Technology, if such party accepts inclusion of such Enrichment Technology then the parties shall each pay an amount to be negotiated according to reasonable commercial terms to cover all costs, fees, royalties, or other payments associated with obtaining any rights in obtaining such Enrichment Technology. The distribution of revenues for any products incorporating such Enrichment Technology shall then also be negotiated according to reasonable commercial terms.

c. in the event that the party to whom the information is presented in (a) above declines inclusion of such Enrichment Technology, then the other party shall again offer the inclusion of such technology to the declining party when clinical utility for products embodying such technology has been demonstrated and available data is sufficient to indicate that Clinical Trials for products embodying such technology can be successfully conducted. If the party to whom the information is presented under this section then accepts inclusion of such technology then the party that initially declined inclusion of the Enrichment Technology shall pay to the other party a sum equal to the amount they would otherwise have paid according to (b) above plus the same proportion of any additional costs, fees, royalties, or other payments associated with obtaining such

Enrichment Technology. The distribution of revenues for any products incorporating such Non Platform Technology shall then also be negotiated according to reasonable commercial terms.

d. in the event that the party to whom the information is presented in (c) above declines the inclusion of such technology then the provisions of Section 7.3.3 (d) shall apply with respect to Enrichment Technology.

## 8. PATENTS

8.1 Prosecution. Each party shall promptly report to the other all Inventions whether or not such inventions are patentable. OCD and Immunicon shall jointly select Inventions jointly made for which they wish to file patent applications or perfect other intellectual property rights therein and they shall select the countries where they wish to have patent applications filed or patents maintained. Upon such selection, Immunicon shall, using patent counsel of its choice, reasonably acceptable to OCD, take all necessary steps to file, prosecute and maintain, the requested patent protection on such joint Inventions. Either party shall have the right upon thirty (30) days prior written notice to the other party, at its sole cost and expense, to file and prosecute a patent application or maintain a patent covering all or a part of any jointly-held Invention in any country which such other party does not select as set forth above, unless upon receipt of such notice and before the end of the notice period, such other party selects such country.

8.2 Each party shall provide to the other copies of all applications covering joint Inventions, all prior art searches relating to such patent applications, and all correspondence to and from the United States Patent and Trademark Office relating to the same. Upon request, the party prosecuting a patent application shall make available to the other party all related correspondence with other patent offices.

8.3 Immunicon shall promptly inform OCD of all patent applications filed on its Inventions and shall provide to OCD copies of all such applications, all prior art searches relating to such patent applications, and all correspondence to and from the United States Patent and Trademark Office relating to the same. Upon the request of OCD, Immunicon shall make available to OCD related correspondence with other patent offices.

8.4 OCD shall promptly inform Immunicon of all patent applications filed on its Inventions in the Field and shall provide to Immunicon copies of all such applications, all prior art searches relating to such patent applications, and all correspondence to and from the United States Patent and Trademark Office relating to the same. Upon the request of Immunicon, OCD shall make available to Immunicon related correspondence with other patent offices. For the resolution of doubt, the obligations set forth in this section 8.5 shall only apply to the patent applications of OCD and shall not apply to any patent applications filed or prepared by an Affiliate of OCD.

8.5 The parties shall obtain or perfect rights in Works according to mutually agreed terms.

8.6 Assuming Prosecution.

8.6.1 Immunicon Inventions. In the event that Immunicon wishes to discontinue or abandon prosecution of any patent or patent application in the Field, or elects to cease paying maintenance fees of any resulting patent, it shall promptly inform OCD; OCD shall then be entitled to continue the prosecution of any such application, pay any expense or cost, and take any other action necessary to continue the prosecution of such patent applications or keep any resulting patents in force on behalf of Immunicon. In the event that any Cellular Analysis Product or Automated Cell Analysis System subsequently released into the stream of commerce comes within the scope of any patent whose prosecution or maintenance has been so assumed by OCD, then Immunicon shall refund to OCD the reasonable out of pocket costs borne by OCD in taking such actions with respect to the patent(s) in question.

8.6.2 Joint Inventions. In the event that a party wishes to discontinue or abandon prosecution of any patent or patent application on any joint Invention, or elects to cease paying maintenance fees of any resulting patent, it shall promptly inform the other party; such other party shall then be entitled to continue the prosecution of any such application, pay any expense or cost, and take any other action necessary to continue the prosecution of such patent applications or keep any resulting patents in force on behalf of the parties. In the event that any Cellular Analysis Product or Automated Cell Analysis System subsequently released into the stream of commerce comes within the scope of any patent whose prosecution or maintenance has been so assumed, then the party that elected to discontinue or abandon prosecution or maintenance shall refund to the other party the costs borne by the other party in taking such actions with respect to the patent(s) in question.

8.7 Costs. All patent attorney fees and all patent registration, patent filing, patent translation and patent maintenance fees, costs and expenses with respect to the Patents and the Inventions solely owned by a party shall be borne by that party. All such fees, costs, and expenses with respect to Patents and the Inventions owned jointly by the parties shall be shared equally by the parties.

8.8 In all events concerning patent prosecution of the application under this Section, OCD and Immunicon shall cooperate with each other.

## 9. Third Party Infringement.

9.1 Enforcement by Immunicon. If either party becomes aware that any of the Patents or rights in Works are being or have been infringed by any Third Party, such party shall promptly notify the other party hereto in writing describing the facts relating thereto in reasonable detail. Immunicon shall have the initial right, but not the obligation, to institute, prosecute and control any action, suit or proceeding (an "Action") with respect to such infringement, including any declaratory judgment action, at its expense, using counsel of its choice. OCD shall cooperate with Immunicon and provide such nonmonetary assistance as Immunicon may reasonably request in connection with any such Action. Any recovery of damages by Immunicon for any such suit shall be applied first in satisfaction of any costs incurred by Immunicon relating to the Action (including attorneys' and expert fees and the balance remaining from any recovery shall be divided as follows: (a) OCD shall recover sixty nine percent (69%), and (b) all the remaining damages shall be recovered by Immunicon.



9.2 Joint Enforcement. In the event that Immunicon institutes an Action relating to the Field pursuant to Section 9.1 above, OCD shall have the right to intervene in such Action and Immunicon shall not oppose such intervention, provided that (i) OCD notifies the court of its intention to intervene within one hundred twenty (120) days of the commencement of such Action, and (ii) OCD shares equally with Immunicon the total costs incurred by Immunicon (including, without limitation, attorneys' and expert fees) of conducting such Action. The parties shall cooperate and provide each other such assistance as either may reasonably request in connection with any such Action, provided, Immunicon shall retain the control of the conduct and settlement of any such Action. Any recovery of damages for any such suit shall be applied first in satisfaction of any actual out-of-pocket costs and expenses incurred by either of the parties relating to the Action (including, without limitation, attorneys' and expert fees), the balance remaining from any recovery shall be divided as follows: (a) OCD shall recover sixty nine percent (69%), and (b) all the remaining damages shall be recovered by Immunicon.

9.3 Enforcement by OCD. In the event that Immunicon fails to initiate or defend any Action involving the Patents or rights in Works in the Field within one hundred eighty (180) days of receiving notice of any alleged infringement, OCD may, at its option, initiate and control such an Action (including Actions for past infringements), and Immunicon shall cooperate with OCD and provide such non-monetary assistance as OCD may reasonably request in connection with any such Action. Any recovery of damages by OCD for any such suit shall be applied first in satisfaction of any costs incurred by OCD relating to the Action (including attorneys' and expert fees), the balance remaining from any recovery shall be divided as follows: (a) OCD shall recover sixty nine percent (69%), and (b) all the remaining damages shall be recovered by Immunicon. In addition to the foregoing, OCD shall have the right to be included as a co-plaintiff or named plaintiff in any litigation involving Inventions in the Field for the purpose of calculating and obtaining damages due under the law or in equity adequate to compensate OCD for its losses.

9.4 Costs. The costs of litigation referred to in this Section 9 shall include but not be limited to such out-of-pocket expenses as court costs and court fees, reasonable travel expenses, reasonable charges for the professional services of outside counsel and experts, and shall exclude only the time that OCD's or Immunicon's regular employees devote to such litigation.

9.5 Assistance. Immunicon agrees that in the event that OCD chooses to prosecute an action for infringement of a Patent under Section 9.3 herein but cannot do so in its own name, to sign and give to, within thirty (30) days after request by OCD, all necessary documents in order for OCD to prosecute such infringement in the name of Immunicon. Immunicon also agrees to cooperate with OCD, at OCD expense for out-of-pocket costs, in the prosecution of such infringement.

#### 10. Third Party Claim of Infringement.

10.1 If a claim of patent infringement or misappropriation or wrongful use of a trade secret or other proprietary right is brought against a party hereto in any country by reason of any act conducted in

the furtherance of this Agreement, or if a party becomes aware of any potentially-infringing patent or other proprietary right owned by a Third Party in any country, such party shall promptly give notice thereof to the other parties and provide them with all information in its possession regarding such claim or potential infringement.

10.2 Each party shall indemnify, defend and hold harmless the other party against any damages, costs, expenses and liabilities (including attorneys' fees and expenses) arising out of a claim of patent infringement or misappropriation or wrongful use of a trade secret or other proprietary right based on the manufacture, use, or anticipated sale of any product that embodies the indemnifying party's Invention or Works. The indemnifying party shall conduct the defense of any such suit for infringement, misappropriation, or misuse at its expense. The indemnified party may participate in such defense, at its option and expense, and shall furnish to the indemnifying party such assistance as it may reasonably need and request from time to time for the conduct of the defense of such suit. Neither party shall dispose of or settle any such claim in any manner which may compromise or affect the validity of any of the other party's Inventions or Works, without that party's prior written consent, which shall not be unreasonably withheld. No indemnification of any claim for infringement, misappropriation, or misuse shall apply where the claim arises out of the manufacture, use, or anticipated sale of products embodying joint Inventions or Works.

11. **Patent Marking.** OCD shall mark Cellular Analysis Products with appropriate patent numbers or indicia at Immunicon's instruction and election, as, when and where OCD may reasonably accommodate same, given packaging, printing schedules and other factors, in those countries where such markings have notice value as against infringing persons.

## 12. **Confidentiality and Publication**

12.1 **Confidential Information.** All Confidential Information disclosed by one party to the other shall not be used by the receiving party except in connection with the activities contemplated by this Agreement, shall be maintained in confidence by the receiving party, and shall not be disclosed by the receiving party to any other person, firm or agency, governmental or private, without the prior written consent of the disclosing party, except to the extent Confidential Information is:

- (1) known by or in possession of the receiving party at the time of its receipt as documented in written records;
- (2) independently developed outside the scope of this Agreement by employees of the receiving party having no access to or knowledge of the Confidential Information disclosed hereunder as documented in written records;
- (3) in the public domain at the time of its receipt or thereafter becomes part of the public domain through no fault of the receiving party;
- (4) received without an obligation of confidentiality from a Third Party having the right to disclose such information;

(5) required to be disclosed to governmental agencies in order to gain approval to sell Cellular Analysis Products and Automated Cell Analysis Systems, or disclosure is otherwise required by law, regulation or governmental or court order (so long as the receiving party provides notice of such disclosure, seeks to obtain protective orders or other available confidentiality treatment and, in the case of disclosures to the SEC, seeks confidential treatment to the extent reasonably requested by the disclosing party);

(6) released from the restrictions of this Section 12.1 by the express written consent of the disclosing party; or

(7) disclosed to agents, consultants, assignees, sublicensees or subcontractors of OCD or Immunicon or their Affiliates which have a need to know such information in connection with the performance of this Agreement, provided that such persons are or agree to be subject to the provisions of this Section 12.1 or substantially similar provisions.

12.2 Publication. Prior to public disclosure or submission for publication of a manuscript or other work describing the result of any aspect of the Development Program or other scientific or clinical activity or collaboration between OCD and Immunicon relating to any activity under the terms of this Agreement, the party disclosing or submitting such a manuscript ("Disclosing Party") shall send the other party ("Responding Party") a copy of the manuscript to be submitted and shall allow the Responding Party not less than thirty (30) calendar days in which to determine whether the manuscript contains subject matter for which patent protection should be sought prior to publication of such manuscript for the purpose of protecting an invention of commercial value to the Responding Party, or whether the manuscript contains confidential information belonging to the Responding Party, or whether the manuscript contains information that should not yet be revealed for other business reasons. After the expiration of such thirty (30) calendar day period, if the Responding Party has not objected, the Disclosing Party may submit such manuscript for publication and publish or otherwise disclose to the public such research results. If the Responding Party believes the subject matter of the manuscript contains confidential information or a patentable invention of commercial value to the Responding Party or should not yet be otherwise revealed, then prior to the expiration of such thirty (30) calendar day period, the Responding Party shall notify the Disclosing Party in writing of its determination. Upon receipt of such written notice from the Responding party, the Disclosing Party shall delay public disclosure of such information or submission of the manuscript for an additional period of sixty (60) calendar days to permit preparation and filing of a patent application on the disclosed subject matter or for such other period and for such other reasons as the parties shall mutually agree. The Disclosing Party shall thereafter be free to publish or disclose such information, except that the Disclosing Party may not disclose any confidential information of the Responding Party without the prior written consent of the Responding Party.

### 13. TERM, TERMINATION, AND REMEDIES FOR CERTAIN BREACHES

13.1 Term. Unless earlier terminated in accordance with this Section 13, this Agreement shall remain in effect until twenty (20) years following the Effective Date hereof and the term of this

Agreement shall automatically extend for three-year renewal terms unless otherwise terminated in accordance with this Section 13.

13.2 Termination of Manufacturing and Research Obligations by Immunicon. Immunicon shall have the right to provide OCD with three years notice of termination of its obligation to supply products and/or conduct research no earlier than seventeen (17) years from the Effective Date hereof in which case Immunicon shall be relieved of such obligations. In the event that Immunicon terminates its obligations to supply products and/or conduct research, Immunicon's share of Net Sales will be adjusted as set forth in Sections 6.6.1 and/or 6.6.2 and/or 6.6.3, as applicable. In the event that Immunicon gives notice to OCD pursuant to this Section 13.2 of its intent to cease supplying products within ninety (90) days of such notice Immunicon shall provide OCD with all manufacturing information and know-how and such other assistance as is reasonably necessary to enable OCD to manufacture such products and OCD shall have the right to manufacture or cause a Third Party to manufacture any Cellular Analysis Products or Automated Cell Analysis System, or any component thereof.

13.3 Termination by Mutual Agreement. This Agreement may be terminated at any time upon the mutual agreement of the parties in writing.

13.4 Termination by OCD Prior to Commercial Period. OCD may terminate this Agreement for any reason or no reason at any time prior to the commencement of the Commercial Period upon one hundred eighty (180) days written notice to Immunicon.

13.5 Termination during the Commercial Period. OCD may terminate this Agreement for any reason or no reason upon twenty-four (24) months' written notice to Immunicon after the commencement of the Commercial Period. Immunicon may terminate this Agreement and/or negotiate with other potential licensees at any time after receiving OCD's notice of termination under this section 13.5.

13.6 Termination for Breach. In the event of a Material Breach by either party, then the other party may terminate this Agreement by giving such party notice of such Material Breach. The party receiving such notice shall have ninety (90) days from the date of receipt thereof to cure such Material Breach. If such Material Breach is not cured within such ninety (90) day period, then the non-breaching party shall have the right to terminate this Agreement effective as of the end of such period. In the event such Material Breach is cured during such period, such notice shall be of no force or effect and this Agreement shall not be terminated.

13.7 Change of Control. In the event that a Third Party who in the immediately preceding fiscal year either has reported or it is generally recognized has recorded medical *in vitro* diagnostic revenues of U.S. \$100,000,000 (the "Acquiring Party") shall acquire by stock purchase, merger or otherwise, directly or indirectly, fifty percent (50%) or more of the outstanding shares entitled to vote for the election of directors of Immunicon, or substantially all of its assets to which this Agreement relates, OCD shall have the right, within sixty (60) days after such acquisition, to terminate this Agreement upon thirty (30) days notice to the Acquiring Party and to Immunicon, except as otherwise required by law.

**13.8 Effect of Termination.** (a) In the event of termination of this Agreement pursuant to Section 13.4 or Section 13.6 (in the event that OCD is the breaching party), OCD shall have no rights under the license granted in Section 7.2 and such license shall thereafter be nugatory.

(b) In the event of termination of this Agreement pursuant to Section 13.5 or 13.7, OCD shall have no rights under the license granted in Section 7.2 and such license shall thereafter be nugatory unless, at its sole option, OCD shall pay to Immunicon all Milestone payments (whether or not such Milestones have been achieved) in which case such exclusive license shall be reduced to, and OCD may retain, a sole license with Immunicon such that Immunicon shall have the world-wide right to make, use, and sell Cellular Analysis Products and Automated Cell Analysis Systems with the right to have the same sold and/or distributed by one entity (other than OCD) in each country and to perform such other activities as required in connection with, or incidental to, such selling and distribution activity; provided, however, that in the event of termination of this Agreement pursuant to Section 13.7, such license shall be exclusive for the five-year period commencing with the effective date of such termination. In the event that pursuant to this clause (b) OCD retains such a sole license or exclusive license, as the case may be, it shall pay to Immunicon an amount equal to ten percent (10%) of Net Sales subject to the adjustment set forth in Section 6.6.2; provided, however, that in the event of termination of this Agreement pursuant to Section 13.7, such amount shall be reduced to seven percent (7%) of Net Sales (fifty percent of which shall be attributable to each of Patents and Know How) for the period during which such license is a sole license, subject to the adjustment set forth in Section 6.6.2.

(c) In the event of termination of this Agreement pursuant to Section 13.6 (in the event that Immunicon is the breaching party), OCD shall have no rights under the license granted in Section 7.2 and such license shall thereafter be nugatory unless, at its sole option, OCD shall pay to Immunicon all Milestone payments (whether or not such Milestones have been achieved) in which case such exclusive license shall be retained by OCD. In the event that OCD retains such an exclusive license it shall pay to Immunicon an amount equal to seven percent (7%) of Net Sales (64 percent of which (i.e., 4½%) shall be attributable to Patents and 36% of which (i.e., 2½%) shall be attributable to Know How) subject to the adjustment set forth in Section 6.6.2 (except that Immunicon's share of Net Sales shall be that percentage of Net Sales otherwise due to Immunicon pursuant to this Agreement, less four and one half percent (4 ½%)).

(d) Termination of this Agreement for any reason shall not release any party hereto from any liability (or obligation assumed and substantially undertaken but not yet accrued) which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination, nor preclude either party from pursuing any rights and remedies it may have hereunder at law or in equity which accrued or are based upon any event occurring prior to such termination, subject to any limitations on damages expressly set forth herein. For the resolution of doubt, upon termination no payment shall be due for any milestone (as defined in Section 5) not yet accomplished. Upon termination or expiration of this Agreement OCD will use reasonable efforts (which shall in no event include the payment of any transfer or other fee) to transfer any Cellular Analysis Product and/or Automated Cell Analysis System product registrations that may have been registered in the name of OCD or any of its Affiliates as well as any trademarks (excluding any trademarks containing the "Oriho" name or logo or the name or logo of any Affiliate of OCD or that was otherwise owned by OCD or its Affiliates prior to the Effective Date).



**13.9 Immunicon's Obligations With Respect to Third Party Patents.** In the event that OCD exercises its right to manufacture or have manufactured any Cellular Analysis Product or Automated Cell Analysis System as set forth in this Agreement, Immunicon will use reasonable commercial efforts to provide OCD with rights under Third Party patents, absent which the manufacture, use or sale of such Cellular Analysis Products or Automated Cell Analysis Systems would infringe valid claims of such patents.

**13.10 Remedies for Certain Breaches.**

**13.10.1 Failure to Perform by Immunicon.** The following acts shall not be considered as giving rise to a right to terminate this Agreement under Section 13.6, but shall comprise a failure to perform by Immunicon which shall have the described consequences: (a) Immunicon's failure to meet manufacturing quality standards as set forth in Section 6.10, which failure Immunicon has failed to remedy or pursue the appropriate course of action as provided in such Section, in which case (i) Immunicon shall provide OCD, upon OCD's request, with all manufacturing information and Know How and such other assistance that is reasonably necessary to enable OCD to manufacture or have manufactured such products and OCD shall have the right to manufacture or cause to be manufactured any Cellular Analysis Products or Automated Cell Analysis System, or any component thereof, and (ii) Immunicon's share of Net Sales from and after the date that Immunicon ceases manufacturing products hereunder shall be as set forth in Section 6.6.1 (as it may be modified by Section 6.6.2); (b) Immunicon's failure to supply as set forth in Section 6.11.1, which failure Immunicon has failed to remedy as provided in such Section, in which case (i) Immunicon shall provide OCD, upon OCD's request, with all manufacturing information and Know How and such other assistance as is reasonably necessary to enable OCD to manufacture or have manufactured such products and OCD shall have the right to manufacture or cause to be manufactured any Cellular Analysis Products or Automated Cell Analysis System, or any component thereof and (ii) Immunicon's share of Net Sales from and after the date that Immunicon ceases manufacturing products shall be as set forth in Section 6.6.1 (as it may be modified by Section 6.6.2); and (c) Immunicon's failure to meet its Research funding obligations under Section 3.5.4, which is not remedied as provided in such Section, in which case OCD may elect, in its sole and absolute discretion to either (i) fund such activities and responsibilities and elect to recoup such funding as provided in Section 3.5.4 or (ii) reduce Immunicon's share of Net Sales as set forth in Section 6.6.3.

**13.10.2 Failure to Perform by OCD.** The following acts shall not be considered as giving rise to a right to terminate this Agreement under Section 13.6, but shall comprise a failure to perform by OCD which shall have the described consequences: (a) OCD's failure to make a product available for sale in a country within six full calendar months after the date of Regulatory Approval within such country (provided that such product is produced in sufficiently reasonable commercial quantities (other than due to the fault of OCD) to enable OCD to make such product available and such sale is not otherwise proscribed), unless on advice of counsel the sale or use of such product would infringe a Third Party patent or other proprietary right in such country or the manufacture of such product would infringe a Third Party patent or other proprietary right in the country in which it is then being manufactured, in which case (i) Immunicon shall have the right to



declare the license set forth in Section 7.2 a sole license in such country and shall have the right to appoint one entity (in addition to OCD) to distribute products in such country and (ii) Immunicon's share of Net Sales shall be as set forth in Section 6.6.4 (as it may be modified by Section 6.6.2); (b) OCD's breach of Section 15.7 in any country, in which case (i) Immunicon shall have the right to declare the license set forth in Section 7.2 a sole license and shall have the right to appoint one entity (in addition to OCD) to distribute the products in such country and (ii) Immunicon's share of Net Sales shall be as set forth in Section 6.6.4 (as it may be modified by Section 6.6.2); and (c) total Net Sales actually achieved in any Major Region during any Calendar Year is less than fifty percent (50%) of the Annual Forecast provided by OCD pursuant to Section 6.7.6 for such Major Region for two (2) consecutive and complete Calendar Years following the third year after the first offer for commercial sale of a product in such Major Region, in which case Immunicon shall have the right to co-market Cellular Analysis Products and Automated Cell Analysis Systems in such Major Region.

#### 14. DISPUTE RESOLUTION

14.1 In the event that Immunicon disagrees with an SC decision regarding the attainment of a Milestone (or failure thereof) or the satisfaction of Milestone conditions (or the failure thereof) it shall have the right to bring forward additional information regarding such Milestone and have the matter reconsidered by the SC within thirty (30) calendar days from the date of the initial SC decision. If, thereafter, Immunicon is still in disagreement with such decision it shall have the right to have the matter decided by a technical expert. Such technical expert shall be selected by the mutual agreement of one technically skilled person selected by Immunicon and one technically skilled person selected by OCD. Neither the technically skilled persons nor the technical expert shall be the employee of either party, nor shall they be a direct competitor of either party, nor shall they have any significant business affiliation with either party. To the extent possible, the technical expert shall base his opinion solely on the technical merits of the matter under consideration. The technical expert shall set forth his decision and reasons for reaching such decision in a written report to the parties. The decision of the technical expert shall be final and both parties waive any right they may otherwise have in arbitration or litigation regarding the merits of such decision. Immunicon shall have the right to initiate the process of selecting technically skilled persons and technical experts at any time following the first decision by the SC regarding the attainment of a Milestone but no decision shall be rendered until such decision has been reconsidered by the SC as set forth above. The parties shall each share equally in all costs associated with the performance of the technical expert and shall each bare their own expenses in all other respects.

14.2 Any controversy or claim arising out of or relating to this Agreement or the validity, inducement, or breach thereof (other than any controversy or claim regarding the attainment of a Milestone which shall be settled in accordance with the procedures set forth in Section 14.1), shall be settled by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining, except where those rules conflict with this provision, in which case this provision controls. The parties hereby consent to the jurisdiction of the Federal District Court for the Southern District of New York for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction shall enforce this clause and enter

judgment on any award. The arbitrator shall be an attorney who has at least 15 years of experience with a law firm or corporate law department of over 25 lawyers or was a judge of a court of general jurisdiction. The arbitration shall be held in New Jersey and the arbitrator shall apply the substantive law of New York (except where the law conflicts this clause) except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. The arbitrator shall be neutral, independent, disinterested, impartial and shall abide by the Code of Ethics for Arbitrators in Commercial Disputes approved by the AAA. Within 45 days of initiation of arbitration, the parties shall reach agreement upon and thereafter follow procedures assuring that the arbitration will be concluded and the award rendered within no more than six months from selection of the arbitrator. Failing such agreement, the AAA will design and the parties will follow procedures that meet such a time schedule. Each party has the right before or, if the arbitrator cannot hear the matter within an acceptable period, during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration. THE ARBITRATOR SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES, AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES. NO PARTY MAY SEEK OR OBTAIN PREJUDGMENT INTEREST OR ATTORNEYS' FEES OF COSTS.

#### 15. REPRESENTATIONS, INDEMNIFICATION, NON-COMPETITION COVENANTS

##### 15.1 Representations of Immunicon. Immunicon represents and warrants to OCD that:

15.1.1 The execution, delivery and performance of this Agreement by Immunicon will not, with or without notice, the passage of time or both, result in any violation of, be in conflict with, or constitute a default under any contract, obligation or commitment to which Immunicon is a party or by which it is bound, or to Immunicon's knowledge, any statute, rule or governmental regulation applicable to Immunicon.

15.1.2 Immunicon has all requisite legal and corporate power and authority to enter into this Agreement and to carry out and perform its obligations under the terms of this Agreement. All corporate action on the part of Immunicon and its officers, directors and stockholders necessary for the performance of Immunicon's obligations hereunder has been taken. This Agreement constitutes a valid and binding obligation of Immunicon, enforceable in accordance with its terms, except as (i) the enforceability hereof may be limited by bankruptcy, insolvency, moratorium or other similar laws affecting the enforcement of creditors' rights and remedies generally, (ii) the availability of equitable remedies (e.g., specific performance, injunctive relief, and other equitable remedies) may be limited by equitable principles of general applicability, and (iii) that no representation is made regarding the effect of laws relating to competition, antitrust or misuse or the effect of OCD's intellectual property rights.

15.1.3 All employees of Immunicon who are expected to participate in the Development Program have signed agreements regarding proprietary information and inventions, confidentiality and non-use of information with Immunicon in a form reasonably

considered by Immunicon and its counsel to assure Immunicon's title to any Inventions or Confidential Information that may arise or be developed by such employees hereunder. Such agreements are legal, valid and binding obligations of Immunicon and its employees and are enforceable in accordance with their terms, except as limited by applicable bankruptcy laws and other similar laws affecting the creditors' rights and remedies generally and except insofar as the availability of equitable remedies may be limited.

15.1.4 To the knowledge of Immunicon, as of the Effective Date of this Agreement, Cellular Analysis Products, Automated Cell Analysis Systems and related instrumentation and materials in development and contemplated development on the date hereof, can be manufactured, produced, used, sold and distributed without infringing the patents or other proprietary rights of any other party.

15.1.5 Immunicon has obtained rights relating to Cellular Analysis Products, Automated Cell Analysis Systems, and related instrumentation and materials that may have been affected by collaborations between Immunicon and Third Parties wherein such rights are necessary for the performance hereunder by Immunicon and OCD. Such collaborations include, without limitation, efforts undertaken with, Becton Dickinson, The University of Texas Southwestern Medical Center, and The University of Twente.

15.2 Representations of OCD. OCD represents and warrants to Immunicon that:

15.2.1 Its execution, delivery and performance of this Agreement will not, with or without notice, the passage of time or both, result in any violation of, be in conflict with, or constitute a default under any contract, obligation or commitment to which it is a party or by which it is bound, or to its knowledge, any statute, rule or governmental regulation applicable to it.

15.2.2 OCD has all requisite legal and corporate power and authority to enter into this Agreement and to carry out and perform its obligations under the terms of this Agreement. All corporate action on the part of OCD and its officers and directors necessary for the performance of its obligations hereunder has been taken. This Agreement constitutes a valid and binding obligation of each such party, enforceable in accordance with its terms, except as (i) the enforceability hereof may be limited by applicable bankruptcy laws and other similar laws affecting creditors' rights and remedies generally, (ii) the availability of equitable remedies (e.g. specific performance, injunctive relief and other equitable remedies) may be limited by equitable principles of general applicability, and (iii) that no representation is made regarding the effects of laws relating to competition, antitrust or misuse.

15.2.3 OCD, as of the Effective Date, is not a party to any material contract (other than this Agreement) with a Third Party with respect to the Field.

15.3 Indemnification by OCD. OCD shall at all times, during the term of this Agreement and thereafter, indemnify and hold harmless Immunicon and its Affiliates, stockholders, directors, officers, agents and employees from any claim, proceeding, loss, expense, and liability of any kind

whatsoever (including but not limited to those resulting from death, personal injury, illness or property damage and including legal expenses and reasonable attorneys' fees) (collectively, "Damages") arising out of or resulting from (a) the misrepresentations of any representation or the breach of any warranty, covenant or agreement made by OCD in this Agreement and (b) the negligence or willful misconduct of OCD or any of its Affiliates or any of their respective subagents in connection with any such entity acting as a sales agent for Automated Cell Analysis Systems under Section 6.4.1; provided, however that there shall be apportionment in accordance with responsibility when such indemnity obligation derives in part from acts of OCD and in part from acts of Immunicon (and the parties hereby agree to split all third party product liability or personal injury claims arising from the sale, use or distribution of any Cellular Analysis Product or Automated Cell Analysis System that meets the Specifications therefor and is not otherwise defective as agreed to by the parties and if the parties are unable to reach such agreement then such matter shall be determined in accordance with the procedures set forth in Section 14.2 and the arbitrator shall make such determination in accordance with the relative fault of the parties); provided, further, however, Immunicon shall bear all Damages which arise out of or result from the sale, use or distribution of any Cellular Analysis Product or Automated Cell Analysis System that does not meet the Specifications therefor or is otherwise defective or not consistent with any warranty as to Bulk Reagents or Automated Cell Analysis System made by Immunicon hereunder.

**15.4 Indemnification by Immunicon.** Immunicon shall at all times, during the term of this Agreement and thereafter, indemnify and hold harmless OCD and its Affiliates, stockholders, directors, officers, agents and employees from any claim, proceeding, loss, expense, and liability of any kind whatsoever (including but not limited to those resulting from death, personal injury, illness or property damage and including legal expenses and reasonable attorneys' fees) arising out of or resulting from (a) the misrepresentation of any representation or the breach of any warranty, covenant or agreement made by Immunicon in this Agreement and (b) the negligence or willful misconduct of Immunicon or any of its employees or agents in connection with the clinical trial activities undertaken by Immunicon pursuant to this Agreement; provided, however, that there shall be apportionment in accordance with responsibility when such indemnity obligation derives in part from acts of OCD and in part from acts of Immunicon.

**15.5 Claims.** In any claim for indemnification (an "Indemnity Claim"), the indemnified party agrees to give the indemnifying party prompt written notice of any matter upon which such indemnified party intends to base such a claim under this Agreement. The indemnifying party shall have the right to participate jointly with the indemnified party in the indemnified party's defense, settlement or other disposition of any Indemnity Claim. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the indemnified party's becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the indemnified party in any manner, and as to which the indemnifying party shall have acknowledged in writing the obligation to indemnify the indemnified party hereunder, the indemnifying party shall have the sole right to defend, settle or otherwise dispose of such Indemnity Claim, on such terms as the indemnifying party, in its sole discretion, shall deem appropriate; provided that the indemnifying party shall provide reasonable evidence of its ability to pay any damages claimed and with respect to any such settlement shall obtain the written release of the indemnified party from the Indemnity Claim. The indemnifying party shall obtain the written consent of the indemnified party prior to ceasing to defend, settling or otherwise disposing of any

Indemnity Claim if as a result thereof the indemnified party would become subject to injunctive or other equitable relief or the business of the indemnified party would be adversely affected in any manner. In the event that any such indemnity obligation shall be apportioned between the parties, OCD shall have the right to control the Indemnity Claim, subject to the participation and involvement of Immunicon.

15.6 Insurance. Each party agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby which policies shall provide for the types of and amounts of coverage as set forth in Schedule 15.6 attached hereto. Each policy shall provide for 30 days written notice of cancellation or material change and upon request, each party shall provide to the other party a certificate of coverage or other written evidence reasonably satisfactory to such other party of such insurance coverage

15.7 Non-competition Covenant. During the term of this Agreement, neither OCD or its Affiliates on the one hand, nor Immunicon or its Affiliates on the other hand, shall manufacture, promote, market, sell or distribute any products in the Field other than the Cellular Analysis Products and the Automated Cell Analysis System ("Competing Activity"); provided, however, that the foregoing shall not be deemed to prohibit OCD, Immunicon or any of their respective Affiliates from (a) owning or acquiring the securities or assets of any entity where the sales attributable to Competing Activity of such entity does not exceed \$50,000,000 for the twelve-month period immediately preceding the date such securities or assets are owned or acquired, it being understood that if OCD, Immunicon or any of their respective Affiliates should acquire an entity exceeding such limits, they shall have the obligation to dispose of, or otherwise relinquish control of, such competing business within one year after its acquisition or merging it into the business to which this Agreement relates; or (b) owning or acquiring up to twenty percent (20%) of the outstanding voting securities or other equity interests of any entity that has sales attributable to Competing Activity exceeding the limits set forth in clause (a) of this Section.

## 16. MISCELLANEOUS

16.1 Notices. Any notice to be given hereunder by OCD to Immunicon or by Immunicon to OCD shall be in writing and delivered personally, or sent by national overnight delivery service or postage pre-paid registered or certified U.S. mail, and shall be deemed given: when delivered, if by personal delivery or overnight delivery service; or upon if so sent by U.S. mail, three business days after deposit in the mail, and shall be addressed:

If to OCD, to OCD's address set forth above, to the attention of the Chairman;

With a copy to:

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933  
Attention: Office of General Counsel



If to Immunicon to Immunicon's address set forth above, to the attention of the President or to such other address as any party shall hereafter designate by notice given in accordance with this Section.

16.2 Payment of Expenses. Except as expressly set forth herein, all costs and expenses related to this Agreement and the related transactions, including the fees and expenses of legal counsel, accountants, brokers and other representatives and consultants, shall be borne by the party incurring such costs and expenses, whether or not such transactions are consummated.

16.3 Assignment.

16.3.1 Neither this Agreement nor any of the rights, interests or obligations hereunder may be assigned by either party without the prior written consent of the other party which consent shall not be unreasonably withheld; except that (a) OCD may, without such consent, assign this Agreement or any or all of such rights, interests and obligations to (i) any Affiliate thereof or (ii) a Third Party to whom substantially all of OCD's business or assets in the cellular analysis of Cancer is transferred; and (b) Immunicon may assign this Agreement to (i) an Affiliate or (ii) a Third Party to whom substantially all of Immunicon's business or assets (including, without limitation, Inventions) have been assigned, subject to OCD's rights set forth in Section 13.7.

16.3.2 In the event of an assignment of this Agreement pursuant to Section 16.3.1 (a)(ii), the restrictions set forth in Section 15.7 shall no longer apply to OCD or any of its Affiliates. In the event of an assignment of this Agreement pursuant to Section 16.3.1 (b)(ii), the restrictions set forth in Section 15.7 will continue to apply to Immunicon as well as the assignee of this Agreement.

16.3.3 Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, and no other person shall have any right, benefit or obligation under this Agreement as a third party beneficiary or otherwise. Any assignment in contravention of this section 16.3 is void.

16.4 Public Statements and Press Releases. The parties hereto covenant and agree that, except as provided for hereinbelow, each will not from and after the date hereof make, issue or release any public announcement, press release, statement or acknowledgment of the existence of, or reveal publicly the terms, conditions and status of, the transactions contemplated herein, without the prior written consent of the other party as to the content and time of release of and the media in which such statement or announcement is to be made; provided, however, that in the case of announcements, statements, acknowledgments or revelations which either party is required by law to make, issue or release, the making, issuing or releasing of any such announcement, statement, acknowledgment or revelation by the party so required to do so by law shall not constitute a breach of this Agreement if such party shall have given, to the extent reasonably possible, not less than two (2) calendar days prior notice to the other party, and shall have attempted, to the extent reasonably possible, to clear such announcement, statement, acknowledgment or revelation with the other



party. No party shall use the name of the other party or any of its Affiliates for advertising or promotional purposes without the prior written consent of such other party.

16.5 Modifications and Amendments. This Agreement shall not be modified or otherwise amended except pursuant to an instrument in writing executed and delivered by each of the parties hereto.

16.6 Headings. The Article and Section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning and interpretation of this Agreement.

16.7 Waiver. The failure of any party to require the performance of any term of this Agreement, or the waiver of any party of any breach of this Agreement, shall not prevent a subsequent exercise or enforcement of such terms or be deemed a waiver of any subsequent breach of the same or any other term of this Agreement.

16.8 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

16.9 Invalidity. In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, then to the maximum extent permitted by law, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any other such instrument.

16.10 Construction. The parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement. This Agreement shall be governed by the laws of the State of New York, without giving effect to conflicts of law provisions.

16.11 Incorporation of Exhibits and Schedules. The Exhibits and Schedules identified in this Agreement are incorporated herein by reference and made a part hereof. In the event of any conflict between the terms or provisions of any Exhibit or Schedule and those of the basic Agreement, the terms or provisions of the basic Agreement shall govern.

16.12 Entire Agreement. It is the desire and intent of the parties to provide certainty as to their future rights and remedies against each other by defining the extent of their undertakings herein. This Agreement constitutes and sets forth the entire agreement and understanding between the parties with respect to the subject matter hereof and is intended to define the full extent of the legally enforceable undertakings of the parties hereto, and no promise, agreement or representation, written or oral, which is not set forth explicitly in this Agreement is intended by either party to be legally binding. Each party acknowledges that in deciding to enter into this Agreement and to consummate the transactions contemplated hereby it has not relied upon any statements, promises or representations, written or oral, express or implied, other than those explicitly set forth in this Agreement. This Agreement supersedes all previous understandings, agreements and

representations between the parties, written or oral, with respect to the subject matter hereof.


**16.13 Survival of Certain Provisions.** To the extent applicable the following Sections shall survive termination of this Agreement along with any remedies for the breach thereof: Section 6.6 (Adjustments to Distribution of Revenue), 7.1 (Ownership of IP), 7.2 (License Grant), accrued rights under Section 8 (Patents), 9 (Third Party Infringement), 10 (Infringement), 11 (Marking), 12 (Confidentiality), 14 (Dispute Resolution), 15.1.4 (Representations), 15.1.5 (Representations), 15.3 (Indemnification), 15.4 (Indemnification), 15.5 (Claims).

**16.14 No Agency.** Except for the sales agency arrangement set forth in Section 6.4.1, nothing in this Agreement shall be construed to make the relationship of the parties herein a joint venture, an association, a partnership, or make the parties agents of one another. Except as set forth in Section 6.4.1, the parties are not authorized to act as agents of one another as to any matter or to make any representations to any third parties indicating or implying the existence of any such agency relationship and the relationship between the parties shall be that of independent contractors.


**16.15 Rights Upon Insolvency.** All rights and licenses to Inventions and Works granted under or pursuant to this Agreement by one party ("Licensor") to the other party ("Licensee") are, for all purposes of Section 365(n) of Title 11 of the U.S. Code ("Title 11"), licenses of rights to intellectual property as defined in Title 11. Each party agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such Inventions and Works. If a case is commenced by or against any party hereto under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, such party (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall either perform all of the obligations provided in this Agreement to be performed by such party or provide to the other party all such intellectual property (including all embodiments thereof) held by such party and such successors and assigns, as the other party may elect in a written request, immediately upon such request. If a Title 11 case is commenced by or against a party, this Agreement is rejected as provided in Title 11 and the other party elects to retain its rights hereunder as provided in Title 11, then such party (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall provide to the other party all such intellectual property (including all embodiments thereof) held by such party and such successors and assigns immediately upon the other party's written request therefor. All rights, powers and remedies of any party, as a Licensee hereunder, provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, Title 11) in the event of the commencement of a Title 11 case by or against the other party. Licensee, in addition to the rights, powers and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including Title 11) in such event.

IN WITNESS WHEREOF, the parties hereto intending legally to be bound hereby, have each caused this Agreement to be duly executed as of the date first above written.

IMMUNICON CORPORATION

By   
Name: EDWARD L. ERICKSON  
Title: CHAIRMAN, PRESIDENT & CEO

ORTHO-CLINICAL DIAGNOSTICS, INC.

By   
Name: Gerard Vaillant  
Title: Chairman

SCHEDULE AND EXHIBITS

Exhibit

A  
B  
C  
D

Description

Development Plan  
Immunicon In-Licensed Patents  
Milestone Table  
Screening Feasibility Milestone

Schedule

6.1.1  
15.6Insurance

Description

Bulk Reagent Specification

**EXHIBIT A**

Development Plan (subject to modification as determined by the SC in accordance with this Agreement)

The following elements shall, as a minimum, constitute the initial development plan for the years 2000-2007

**Products for Breast Cancer**

**Therapy Monitoring Assay(s)**

- Tumor cell responsiveness to therapy
- Tumor cell characterization

**Recurrence monitoring**

- Increase in tumor cell count following a period of remission
- Tumor cell characterization

**Screening Product(s)**

- Detects the presence of cancerous epithelial cells in the peripheral circulation of subjects

**Products for Colorectal Cancer**

**Therapy Monitoring Assay(s)**

- Tumor cell responsiveness to therapy
- Tumor cell characterization

**Multi-cancer Broad-Based Screening Product(s) for Males and Females**

**Systems**

Analytical module based on Cell Tracks

Sample Processing module

- For 7.5 mL tubes
- For 30 mL tubes

**Exhibit B**

**Patents, Patent Applications, and Know-How Licensed to Immunicon by Third Parties**

1. *The License Agreement between Twente University and Immunivest Corporation signed on 4/25/97 by Immunicon officer Leon Terstappen, VP.*
2. The Exclusive License Agreement between the University of Texas System and Immunicon Corporation, signed on 6/16/99 by Immunicon officer Edward Erickson, Chairman and CEO. This includes United States patent application 09/248,388 and European patent application PCT/US99/03073 (WO99/41613), U. S. Provisional Patent Application Serial Number 60/074,535 filed February 12, 1998 entitled "Test For Detecting, Enumerating and Characterizing Carcinoma Cells in the Blood" (corresponding for reference purposes only to UT Southwest file number UTSD:568-PZ1) and U. S. Provisional Patent Application Serial Number 60/110,202 filed November 30, 1998 entitled "Detection and Characterization of Carcinoma Cells in the Blood" (corresponding for reference purposes only to UT Southwest file number UTSD:568-PZ2).
3. The License Agreement between Stanford University and Immunicon Corporation covering the phycobiliproteins, signed on 2/9/00 by Immunicon officer Edward Erickson, Chairman and CEO. This includes Stanford University dockets:

**S81-026**

**Patent Status:**

- ☐ Issued: 4859582 (USA)
- ☐ Issued: 5055556 (USA)
- ☐ Issued: 4520110 (USA)
- ☐ Issued: 1594827 (Japan)
- ☐ Issued: 76695 (EPO)
- ☐ Issued: 1179942 (Canada)
- ☐ Issued: 548440 (Australia)

**S83-020**

Appears to be docket of continuations of patents

4. Letter agreements from Dr. J. Hilgers, President of Bioprobe BV to Immunicon officer Edward Erickson, Chairman and CEO, in which Bioprobe BV guarantees Immunicon the right to make, use, sell, ... (or have made, used, sold, ...) certain antibodies and hybridomas (VU-1D9, C11, VU-D1, VU-3-C6, VU-4-H5, VU-11-E2, VU-12-E1, and VU-13-F11). These are rights to use the hybridomas and resulting antibodies.

5. The License Agreement between Sloan-Kettering Institute for Cancer Research and Immunicon Corporation for the use of Cell Line SK-BR-3 as a control cell, signed on 2/26/00 by Immunicon officer Anthony Barnes, VP.



6. On August 11, 2000, Immunicon officer, Edward Erickson, Chairman, President and CEO signed an agreement that allows it to use the GA733-2e (the extracellular domain of EpCam) protein from the Wistar Institute for the development of potentially novel monoclonal antibodies. This work might create non-blocking antibodies to the VU-1D9 that will allow dual surface labeling of the cells, allowing the identification and isolation of intact cells with potentially greater specificity. The license allows us to use the protein as defined in US Patent Application 08/413,805 only in the context of raising antibodies.

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**Exhibit C:****Milestone Table**

MS #	Title	Target Date	Adjustment Date	Successful Completion Criteria	Sample Proc.	Detection	Test
1	Upon Completion of Breast Cancer Pre-Clinical	1Q01	12/31/01	Steering Committee approval to begin pivotal Clinical Trial for FDA Reg. approval with operational system.	Semi-automated workstation	Cell Spotter	Pre-Clinical Study at Georgetown and such ancillary studies as may be required
2	Upon Demonstration of "Clinical Sensitivity" for Screening	3Q01	7/1/02	Details in Exhibit D	Semi-automated workstation; large sample volume	Cell Spotter	Details in Exhibit D
3	Readiness of the "Cell Tracks" for Pre-Production	3Q02	7/1/03	Completion of Pre-Production stage in IC Prod. Dev. Process, subject to Steering Committee approval.	NA	Cell Tracks	See Note 1
4	Readiness of the Sample Preparation System for Pre-Production	3Q02	7/1/03	Completion of Pre-Production stage in IC Prod. Dev. Process, subject to Steering Committee approval.	Automated Sample Prep. System	NA	See Note 1
5	FDA Reg. submission for Breast Cancer Therapy Monitoring	2Q02	4/1/03	FDA Regulatory submission completed, approved by SC, and transmitted to FDA	Automated Low Volume SP	Cell Spotter	See Note 2
6	Commercial Readiness for Breast Cancer Therapy	1Q03	12/31/03	Steering Committee approves Prod. Release for Sale of a FDA-approved Breast C. Therapy Monitoring Sys.	Automated Low Volume SP	Cell Tracks	See Note 3.

	Monitoring*							
7	FDA Reg. Submission for Colorectal Cancer Therapy Monitoring	2Q03	4/1/04	FDA Regulatory submission completed, approved by SC, and transmitted to FDA	Automated Low Volume SP	Cell Tracks	See Note 4 See Note 5	
8	FDA Regulatory Submission for Breast Cancer Recurrence Monitoring	1Q04	12/31/04	FDA Regulatory submission completed, approved by SC, and transmitted to FDA	High Volume Automated SP	Cell Tracks	See Note 6	
9	FDA Regulatory Approval for Screening Application	2Q06	7/1/07	FDA Approval of a general population Screening Indication (e.g. Women >25y for Breast Cancer)	High Throughput, High Volume Fully-Automated SP	Fully Automated Reading and Detection	See Note 7 See Note 8 See Note 9	

**Notes re Exhibit C (numbers correspond to Milestones in the table):**

1. Steering Committee, final authority held by OCD, must approve Readiness for Pre-Production, such approval not to be unreasonably withheld.
2. Claim language will be formulated to include (subject to Steering Committee approval, not to be unreasonably withheld): "An in vitro device for the quantitative determination of tumor cells in blood to monitor response to therapy or progression in Stage III or Stage IV breast cancer patients"
3. The following minimum requirements must be met:
  - FDA regulatory approval received
  - Minimum 3 lots of materials manufactured under GMP compliance (or current FDA standard for lots and quality compliance)
  - Demonstrated ability to produce the forecasted quantities of materials
  - Inventory in place for Commercial Launch.
4. Claim language (subject to Steering Committee approval, not to be unreasonably withheld): "An in vitro device for the quantitative determination of tumor cells in blood to monitor response to therapy or progression in colorectal cancer patients".

5. The parties agree that colorectal cancer is contemplated as the 2<sup>nd</sup> indication; any change in target would require mutual consent. A substitute 2<sup>nd</sup> indication should have similar incremental effect on sales.
6. Claim language (subject to Steering Committee approval, not to be unreasonably withheld): "An in vitro diagnostic test for recurrence of breast cancer in patients who have undergone treatment".
7. Claim language (subject to Steering Committee approval, not to be unreasonably withheld): "An in vitro device for the detection of breast cancer in asymptomatic females >25 years of age".
8. The parties can mutually agree to alter this Milestone to one of comparable scope.
9. This Milestone assumes a System that fully automates both sample processing and detection and reading.

**Exhibit D:**  
**Screening Feasibility Milestone (Section 5.2.2)**

**Phase 1. Analytical sensitivity using sample processing of 30 ml blood samples.**

- Demonstrate processing of 30 ml of blood using a Semi-Automated Sample Preparation System and the Cell Spotter Analyzer. Blood will be from women >25 years with a reasonable age and race distribution.
- Using both high (~1000 cells/30ml) and low (~50 cells/30 ml) numbers of control cells, demonstrate at least 75% recovery with a 95% confidence level (n=30).
- Demonstrate that background cell number is <5 cells/30 ml with 95% confidence (n=30).
- Demonstrate that there is a significant difference between both low and high antigen density cell lines and background when cells are spiked at an approximate level of 10 cells/30 ml. Difference should be significant to a 95% confidence interval for each cell line (n=30).
- Demonstrate that blood samples can be preserved for at least 24h. It is understood that the preservative is not a requirement to enter into the next phases.

**Phase 2. Determine the false positive rate of the Immunicon test in women undergoing mammography (local sites).**

- Consent women prior to mammography, including a reasonable cross-section of ages and races (and diurnal/circadian variation to the degree reasonably possible) and collect 30 ml of blood each for examination. Immunicon will separately make an effort to study diurnal/circadian variation.
- Assess the background of the Immunicon test on patients assigned to Category 1: negative and Category 2: benign (non-cancerous) finding. Mammograms will be read by one individual.
- Accrual of subjects ends when the average background level can be statistically predicted to a 95% confidence level with an error of  $\pm 2$  cells/30 ml of blood and determine the Upper Reference Limit of the Immunicon test to 97.5% confidence. Not less than 100 women should be accrued.
- Demonstrate that the % of samples falling above the URL is less than the % positive samples determined by the current standard mammography.
- Mutually agree to develop a plan to investigate mammography negative individuals that are Immunicon positive. Follow-up plans for the Immunicon positive/mammography negative samples should be approved by the steering committee prior to the start of Phase 2.

**Phase 3. Investigate correlation with biopsy analysis (local sites).**

- Consent women who will undergo biopsy, and examine 30 ml of blood from each woman.
- Accrual ends when 30 women having invasive carcinoma of the breast (Stage I -> IV) by biopsy and surgical intervention have been identified and at least 130 total women have



been accrued. Stage, histology type, and ER/PR data should be recorded after surgical intervention.

- The number of false positive results using the Immunicon technology should be less than 25% of the number of false positive mammograms.
- For biopsy-confirmed invasive breast cancer, the sensitivity of the Immunicon test should meet the following requirements\*.
  - Stage I:  $\geq 25\%$  sensitivity
  - Stage II:  $\geq 50\%$  sensitivity
  - Stage III:  $\geq 75\%$  sensitivity
  - Stage IV:  $\geq 75\%$  sensitivity
- The sensitivity and specificity of the Immunicon test should be sufficient for OCD to ask Immunicon to proceed with the development of a screening test that can be used in performance studies and subsequent commercialization. OCD may wish to convene a focus panel for help in assessing the performance of the test relative to marketplace needs.

**Phase 4. Additional criteria**

- The protocols used in Phases 1-3 must be reasonable for a screening assay and consistent with a preliminary User Requirements Document provided by OCD.
- The data generated in Phases 1-3 will be used as input to development of a final User Requirements Document.

\* The parties recognize that the sensitivity of the Immunicon test will likely need to be substantially higher prior to commercialization. These guidelines are for preliminary feasibility only.

**Schedule 6.1.1**

**Bulk Reagent Specifications**

(to be attached upon agreement of the parties)

**Schedule 15.6**

**Insurance Requirements**

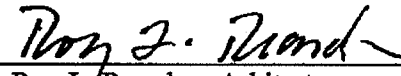
1. Commercial General Liability Insurance in an amount not less than \$5 million per occurrence/annual aggregate bodily injury/property damage combined; provided that such insurance shall be increased to \$10 million per occurrence on or prior to the first commercial sale of Cellular Analysis Products.
2. Product Liability Insurance in an amount not less than \$10 million per occurrence/annual aggregate bodily injury/property damage combined; provided that neither party shall be required to have such insurance in effect until the first commercial sale of Cellular Analysis Products.
3. All Risk Property Insurance covering the full replacement value of the insured's property.
4. Workers Compensation Insurance - statutory limits.

AMERICAN ARBITRATION ASSOCIATION  
(COMMERCIAL ARBITRATION RULES)

IMMUNICON CORPORATION,	)	
	)	
Claimant,	)	Case No. 50 180T 00192 07
	)	
-against-	)	<u>Procedural Order No. 1</u>
	)	
VERIDEX LLC,	)	
	)	
Respondent.	)	

Attached is the Agreed Procedures negotiated between the Parties which will govern the course of this proceeding in accordance with its terms, subject to modifications by agreement, upon application of either Party or the further order of the Arbitrator.

New York, New York  
July 17, 2007

  
\_\_\_\_\_  
Roy L. Reardon, Arbitrator

**Immunicon Corp. v. Veridex , LLC**  
**Proceeding No. 50 180 T 00192 07**

**AGREED PROCEDURES**

1. The parties have agreed upon the following procedures to govern the disposition of this proceeding, subject to further order of the Arbitrator:

July 18, 2007	Discovery period begins (including period for third party discovery).
July 18, 2007	Parties to exchange document requests. <sup>1</sup>
July 23, 2007	Parties to meet and confer to discuss protocols for the production of documents, including electronic documents.
August 3, 2007	Parties to serve objections to document requests.
August 6, 2007	Production on a rolling basis of documents to which there is no objection begins.
August 8, 2007	Parties to meet and confer in a good faith effort to resolve any discovery disputes arising from the parties' objections.
August 24, 2007	Parties to serve privilege logs. Parties to complete production of documents to which there is no objection.
August 31, 2007	Parties to submit any discovery disputes or facial challenges to privilege log entries to the Arbitrator. <sup>2</sup>
September 7, 2007	Parties to respond to each other's notice of discovery disputes and/or challenges to privilege log entries.
Week of September 10, 2007 (subject to arbitrator approval/availability)	Hearing on discovery disputes and privilege challenges.

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<sup>1</sup> This is not intended to foreclose additional document requests or other discovery that may provide an efficient method to exchange meaningful information as events transpire. Although the parties will attempt to agree on any such additional discovery, both sides reserve their rights to object.

<sup>2</sup> This is not intended to foreclose any subsequent challenge to privilege logs or claims to privilege.

Week of September 17, 2007 (subject to arbitrator approval/availability)	Arbitrator to rule on discovery disputes and privilege challenges.
September 28, 2007 (or such other date as is set by the arbitrator or agreed to by the parties) <sup>3</sup>	Parties to complete production of any documents ordered to be produced by Arbitrator's ruling on discovery disputes and privilege challenges.
October 19, 2007	Parties to serve expert reports.
November 9, 2007	Parties to serve any rebuttal expert reports.
November 30, 2007	Discovery period ends.
December 14, 2007	Pre-hearing Briefs to be exchanged.
Date in December 2007 to be fixed by the Arbitrator	Pre-hearing conference.
January 7-25, 2007	Hearings
February 8, 2007	Post-hearing submissions to be completed.
On or before March 3, 2007	Arbitrator to publish award.

2. The purpose of these procedures is to secure the speedy and just resolution of this matter and to assure that an award may be rendered in a timely manner consistent with Section 14.2 of the parties' agreement. The parties stipulate that this schedule shall be deemed to satisfy Section 14.2 of the parties' agreement in all respects.
3. Without prejudice to Section 14.2 of the parties' agreement, the parties agree that hearings may be conducted at the New York offices of Simpson Thacher & Bartlett LLP and that this for all purposes shall be deemed to be conducted in New Jersey and that all legal rights of the parties shall be the same as if the hearings were physically conducted in New Jersey.
4. The Tribunal's Award shall be in writing, shall specify the type of relief given (if any), and shall be a reasoned award.

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<sup>3</sup> The parties recognize that, at this juncture, it is impossible to determine the nature and volume of any additional documents required to be produced by the Arbitrator's order and that the proposed production deadline of September 28, 2007 (and any subsequent deadlines that are dependent upon production being complete by that date) should therefore be treated as provisional.



5. The parties agree that expert reports shall be in a form complying with Fed. R. Civ. P. 26(a)(2)(B) to the extent that there shall be discovery of notes and material considered and/or relied upon by such experts in a manner conforming with federal practice, but that neither party shall be required to produce drafts of expert reports or copies of communications with counsel concerning such drafts. The parties have agreed that there shall not be expert depositions unless it is shown that the report provided with respect to the expert is inadequate.
6. Each party shall be entitled to take 7 party depositions, subject to further depositions being authorized by the Arbitrator for good cause shown. It is acknowledged that neither party has complete knowledge of the number of people knowledgeable about the facts of the present case.
7. The following issues are reserved for further discussion and/or consideration by the Arbitrator:
  - (a) Management of hearing: The parties have discussed but have not agreed upon whether there should be specific time limitations for the presentation of each party's case at the hearing.
  - (b) Witness statements: The parties have discussed but have not yet decided whether witness statements shall be utilized for some or all witnesses, partly or wholly in lieu of direct testimony.

July 16, 2007

**INTERNATIONAL CENTRE FOR DISPUTE RESOLUTION**

-----X		
IMMUNICON CORPORATION,	:	
	:	
Claimant,	:	
	:	Case No.: 50 180T 00192 07
- against -	:	
	:	
VERIDEX LLC,	:	<b>FINAL AWARD</b>
	:	
Respondent.	:	
	:	
-----X		

THE ARBITRATOR having been designated in accordance with the Dispute Resolution provision of the Development, License and Supply Agreement ("DLS Agreement" or "Agreement") entered into between the parties and dated as of August 17, 2000 and having been duly sworn, and having duly heard the proofs and allegations of the parties, does hereby AWARD as follows:

Procedural Background

This Arbitration was commenced on May 31, 2007. After the pleadings were closed, the parties entered into an agreement dealing with the procedures to govern the disposition of this matter as it progressed to conclusion. Procedural Order No. 1 was then issued by the Arbitrator on July 17, 2007 incorporating the agreement of the parties. The parties thereafter engaged in extensive discovery, including the production by both sides of thousands of pages of documents, the exchange of the reports of experts and the taking of depositions. Prior to the commencement of hearings, the Arbitrator was required to issue various Orders with respect to matters upon which the parties could not agree. Following an exchange by the parties of pre-hearing briefs, hearings began on January 7, 2008 and continued thereafter from day to day for 12 sessions

through January 22, 2008. The transcript of the hearings is in excess of 3,600 pages and includes the testimony of expert witnesses.<sup>1</sup> During the hearings the Arbitrator received in evidence several thousands of pages of documents offered by the parties.

Following the completion of the taking of testimony, the parties on February 8, 2008 filed voluminous post-hearing submissions and on February 18, 2008 filed reply briefs. These submissions totaled in excess of 700 pages.

#### The Parties

The Claimant in this proceeding is Immunicon Corporation ("Immunicon"). Immunicon is a Delaware corporation maintaining its corporate headquarters in Huntington Valley, Pennsylvania. It was formed in 1983 and describes itself as a medical biotechnology company engaged in the development, manufacturing, marketing and sale of cell-based diagnostic products focused on cancer. Immunicon is a public company whose stock has been listed on the NASDAQ system since 2004.

The Respondent Veridex LLC ("Veridex") is a limited liability company headquartered in Raritan, New Jersey. It was created in 2003 and is a wholly-owned subsidiary of Johnson & Johnson ("J&J").

J&J is a New Jersey corporation headquartered in New Brunswick, New Jersey. It is a public company and one of the leading manufacturers of health care products and producers of related services, for the consumer, pharmaceutical and medical devices and diagnostic markets in the world.

Ortho-Clinical Diagnostics, Inc. ("OCD") is a New York corporation, having its principal

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<sup>1</sup> Although the DLS Agreement called for hearings to be held in New Jersey, the parties agreed that they could be validly held in New York City at the office of the Arbitrator and be deemed to have been conducted in New Jersey.

office in Raritan, New Jersey. It is also a wholly-owned subsidiary of J&J. OCD was an original party to the DLS Agreement. It is described in the Agreement as an entity having expertise in the marketing, distribution and sale of products used in the diagnosis of human disease states and managing regulatory issues relating to such products.

On November 12, 2003 Immunicon consented to the assignment of and the assumption by Veridex of all the rights, interests and obligations of OCD under the DLS Agreement.<sup>2</sup> This assumption was based upon the representation by Veridex that it was an “Affiliate” of OCD and that the assumption was permitted under § 16.3.1(a)(1) of the Agreement.

#### The Development, License and Supply Agreement

This dispute principally arises out of the DLS Agreement. Summarized here are portions of sections of the DLS Agreement relevant to the issues in this proceeding.

1.2 Immunicon and OCD’s stated intention in entering the DLS Agreement was to “collaborate to produce products based upon their respective technologies and businesses with the intent that a full range of cellular human cancer diagnostics shall be developed and manufactured, in part, by Immunicon and manufactured in part by OCD, and marketed and distributed worldwide by OCD.”

3.1 Development Program. Immunicon was obligated to “conduct Research . . . with the goal of developing” the Cellular Analysis Products and Automated Cell Analysis Systems for commercial sale and to “use its reasonable efforts to conduct the activities for which it [was] responsible in the Development Program.”

#### 3.4. Responsibilities of Immunicon.

3.4.1 Immunicon was responsible for developing the Cellular Analysis Products and Automated Cell Analysis System pursuant to the Development Plan, which was subject to the approval of Veridex.

3.4.2 Immunicon was tasked to “manage, coordinate, implement and administer the Clinical Trials in accordance with the timeline set forth in the Development Plan,” which were to be “conducted in accordance with all applicable legal and regulatory

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<sup>2</sup> As appropriate, by reason of this assignment, references to “OCD” or “Veridex” should be understood in this Award to include the other.

requirements.” Those “Clinical Trials”<sup>3</sup> were to be conducted pursuant to “relevant clinical protocol for a Clinical Trial that is established by the SC.”<sup>4</sup>

3.4.3 Immunicon was to provide “all assistance, consultation and advice as necessary or appropriate in connection with the Clinical Trial for the filing of submissions with Regulatory Authorities, and all other aspects of regulatory approval processes.” It was also required to “use all reasonable efforts to cooperate fully” with Veridex “to comply with and obtain the approval of the Regulatory Authority and all other approvals necessary for [Veridex] to market, sell and distribute products on a worldwide basis.”<sup>5</sup>

### 3.6 Reports and Exchange of Information.

3.6.3 Audit Rights. Each party was given the right, upon reasonable notice to the other and during regular business hours, to inspect and audit the books and records of the other party to assure compliance with the DLS Agreement, as well as to determine Immunicon’s costs in connection with CellSearch reagents to the extent those costs were passed on to Veridex.

## 4. PRE-COMMERCIALIZATION ACTIVITIES.

4.1 Marketing Essential Characteristics. Veridex was required to, in consultation with Immunicon, define the “Marketing Essential Characteristics” for the Cellular Analysis Products and Automated Cell Analysis Systems.<sup>6</sup>

<sup>3</sup> “Clinical Trial(s)” are defined by the DLS Agreement as “human clinical testing meeting the various regulatory requirements and ethical guidelines as may be specified in individual countries where clinical trials of Cellular Analysis Products will be conducted or where such trials will be used to seek approval under Regulatory Authority requirements to market, use and sell Cellular Analysis Products in such country; provided, ‘Clinical Trials’ shall not include post-marketing studies or surveillance.” § 2.

<sup>4</sup> The “SC” or “Steering Committee” was composed of three named representatives of Veridex, three named representatives of Immunicon, and a chairperson, who was to be appointed by Veridex. § 3.2.2. The Steering Committee was “to provide oversight and guidance as to the conduct of the Development Program . . . and to supervise and coordinate the Clinical Trials and the process of obtaining regulatory approvals of” the Immunicon Products. § 3.2.3.

<sup>5</sup> The DLS Agreement does not contain a section specifically delineated “Responsibilities of Veridex,” but rather intersperses those obligations throughout the Agreement. Those provisions are §§ 1.2, 4.1, 4.2, 4.5, 5.1, 5.2, 6.2, 6.4.1(a), 6.4.1(b), 6.4.1(d), 6.4.1(e), 6.4.1(h), 6.7.1., 6.7.2.

<sup>6</sup> “Marketing Essential Characteristic” means the set of properties, characteristics, and functional requirements that must be incorporated in or displayed by Cellular Analysis Products and Automated Cell Analysis Systems or other instrumentation to make them

4.2 Regulatory Approval Submissions. Veridex was required, with the consultation of Immunicon, to make submissions in connection with Regulatory Approvals for any Cellular Analysis Product or Automated Cell Analysis System and to determine when any regulatory filing for such Cellular Analysis Products and Automated Cell Analysis System should be submitted to a Regulatory Authority. Veridex was to have final decision making authority with respect to all regulatory filings, which it was required to file within eight months after completion of the Clinical Trials.

4.5 Filling and Packaging. Veridex was obligated to, at its own expense, provide a facility for filling and packaging Cellular Analysis Products, and to provide a facility for repairing Automated Cellular Analysis Systems.

5. Milestones and Milestone Payments.

5.1 Initial Payment. In partial consideration for the rights and licenses granted in the DLS Agreement, Veridex was required to pay Immunicon, within three business days of the Effective Date of the Agreement, \$1,500,000. Immunicon was required to dedicate \$1,000,000 of that initial payment to Research for Screening Applications. In addition, in order for the Agreement to become effective, Johnson & Johnson Development Corporation ("JJDC") was also required to purchase approximately \$5,000,000 worth of Immunicon stock.

5.2 Milestone Payments. In further consideration of the rights and licenses granted in the DLS Agreement, Veridex was obligated to make nonrefundable "Milestone" payments to Immunicon. The Milestone Payments were to be paid within thirty (30) days after the date that any of the milestones were achieved.<sup>7</sup>

6. COMMERCIAL ACTIVITIES.

6.2 ~~Sharing of Net Sales.~~ Veridex was required to remit to Immunicon 31% of the Net Sales that Veridex recorded each calendar quarter from the sale of Cellular Analysis Products.<sup>8</sup>

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acceptable to [Veridex] and commercially acceptable in the market in which they are intended to be sold." § 2.

<sup>7</sup> These Milestones were adjusted on three occasions on November 10, 2003, January 27, 2005 and December 21, 2005.

<sup>8</sup> Veridex was entitled to keep 69% of Net Sales from the sale of the CellSearch kits.



6.4 Arrangements Relating to Automated Cell Analysis Systems.

6.4.1 Sales Agency Arrangement.

(a) Appointment as Sales Agent. Immunicon appointed Veridex the “exclusive sales, invoicing and collecting agent as well as the exclusive instrument and technical service provider for Automated Cell Analysis Systems,” and Veridex agreed to “contract on behalf of Immunicon for (i) the sale, lease or other transfer of the Automated Cell Analysis System within the Field and (ii) invoice and collect monies due from customers for their purchase, lease or other method of acquisition thereof.”<sup>9</sup>

(b) Authority of each of OCD and its Affiliates as Immunicon’s Agent. Veridex and its Affiliates, acting as sales agents under the DLS Agreement were required to “assess the creditworthiness of potential consumers, and if determined to be acceptable using [Veridex’s] internal standards of commercial judgment ... accept orders and send such accepted orders to Immunicon who will ship the Automated Cell Analysis Systems directly to the customers.”

(d) Sales and Training costs. Veridex was to be responsible for all expenses “which it may incur carrying out its sales and training responsibilities hereunder.”

(e) Promotional Efforts; Materials; Claims; Trademarks. Veridex was responsible for all expenses “which it may incur in marketing, selling and promoting the Automated Cell Analysis System.”

(g) Sales Agency Commission; RAP. Veridex was entitled to receive a sales agency commission of 15% of the amount invoiced to each customer for Automated Cell Analysis System sales, leases or transfers.

(h) Pricing to Customers. Veridex was required to set the price of the Automated Cell Analysis Systems to customers.

6.7 Forecasts and Ordering.

6.7.2 Forecasts. Veridex was to provide Immunicon, at the beginning of each calendar quarter, with a written forecast (the “Forecast”) of Veridex’s expected requirements for CellSearch reagents and Automated Cell Analysis Systems during the four calendar quarters. The first quarter Forecast was to be binding upon both parties with respect to CellSearch reagents only and the

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<sup>9</sup> “‘Field’ means the human *in vitro* application of Cellular Diagnostics to Cancer and Pre-Cancerous conditions. For the resolution of doubt, the Field shall not include cardiovascular diagnostics and screening, neurological disorder diagnostics, infectious disease diagnostics, hematology, standard blood serum immunoassays for soluble markers and analysis of cells taken by tissue biopsy.” § 2.

remaining three quarters were to be for planning purposes only, and not binding on either party.

6.7.6 Annual Forecast. Veridex was required to develop and provide to Immunicon an "Annual Forecast" for North America, Europe and/or Japan, 90 days prior to the commencement of the calendar year, setting forth the number of Automated Cell Analysis Systems and Cellular Analysis Products forecasted to be sold during that year.

6.11 **SUPPLY ASSURANCES; FAILURE TO SUPPLY; FORCE MAJEURE; SECOND MANUFACTURING SITE**

6.11.1 Supply Assurances; Failure to Supply.

(a) Immunicon was obligated to maintain an inventory of CellSearch reagents and Automated Cell Analysis Systems sufficient to "satisfy the Forecast for such products for at least three (3) months based on [Veridex's] requirements for the prior Calendar Year."

7. **INTELLECTUAL PROPERTY**

7.2 License Grant.

7.2.1. Immunicon granted Veridex "a world-wide exclusive right under Immunicon Inventions to make, have made, use, sell and have sold Cellular Analysis Products and Automated Cell Analysis Systems with the Field."

13. **TERM, TERMINATION, AND REMEDIES FOR CERTAIN BREACHES.**

13.1 Term. The contract was to remain in effect for a term of twenty years. It would automatically extend for three-year renewal terms unless otherwise terminated in accordance with § 13 of the Agreement.

13.6 Termination for Breach. The contract could be terminated for "Material Breach."<sup>10</sup> In the event of a Material Breach, "then the other party may terminate this Agreement by giving such party notice of such Material Breach. The party receiving such notice shall have ninety (90) days from the date of receipt thereof to cure such Material Breach. If such Material Breach is not cured within such ninety (90) day period, then the non-breaching party shall have the right to terminate this Agreement effective as of the end of such period. In the event such

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<sup>10</sup> "'Material Breach' means a failure of a party to perform an express covenant or obligation under this Agreement or a breach of a representation or warranty of a party which failure or breach has had or would reasonably be expected to have a material adverse financial consequence to the non-failing or non-breaching party." § 2.

Material Breach is cured during such period, such notice shall be of no force or effect and this Agreement shall not be terminated.”

13.10 Remedies for Certain Breaches.

13.10.2 Failure to Perform by OCD. A “failure to perform” by Veridex would not give rise to the right to terminate the Agreement under § 13.6, unless, *inter alia*, “total Net Sales actually achieved in any Major Region during any Calendar Year is less than fifty percent (50%) of the Annual Forecast provided by [Veridex] pursuant to Section 6.7.6 for such Major Region for two (2) consecutive and complete Calendar Years following the third year after the first offer for commercial sale of a product in such Major Region.” In that case, “Immunicon [would] have the right to co-market Cellular Analysis Products and Automated Cell Analysis System in such Major Region.”

14. DISPUTE RESOLUTION.

14.2 Any dispute arising out of or relating to the DLS Agreement or the validity, inducement or breach thereof (other than any controversy or claim regarding the attainment of a Milestone, which was provided for elsewhere) would be resolved by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association, and in accordance with the substantive law of New York. The arbitrator was required to be an attorney who had at least 15 years of experience with a law firm or corporate law department of over 25 lawyers or was a judge of a court of general jurisdiction. The Agreement further provided “The Arbitrator shall not award any party punitive, exemplary, multiplied or consequential damages, and each party hereby irrevocably waives any right to seek such damages. No party may seek or obtain prejudgment interest or attorneys’ fees [or] costs.”

16. MISCELLANEOUS.

16.12 Entire Agreement. The parties expressed their “desire and intent” that the DLS Agreement “constitutes and sets forth the entire agreement and understanding between the parties with respect to the subject matter hereof and is intended to define the full extent of the legally enforceable undertakings of the parties hereto, and no promise, agreement or representation, written or oral, which is not set forth explicitly in this Agreement is intended by either party to be legally binding. Each party acknowledges that in deciding to enter into this Agreement and to consummate the transactions contemplated hereby it has not relied upon any statements, promises or representations, written or oral, express or implied, other than those explicitly set forth in this Agreement. This Agreement supersedes all previous understandings and representations between the parties, written or oral, with respect to the subject matter hereof.”

16.14 No Agency. The Agreement provided “except for the sales agency arrangement set forth in Section 6.4.1, nothing in this Agreement shall be

construed to make the relationship of the parties herein a joint venture, an association, a partnership, or make the parties agents of one another.”

### The Pleadings

In its Statement of Claim Immunicon asserted claims against Veridex for breach of contract, breach of fiduciary duty and sought various forms of declaratory relief determining its rights and duties under the DLS Agreement.<sup>11</sup>

In more specific detail, the basic claims asserted by Immunicon in its Statement of Claim are:

1. That Veridex violated its representations and its obligation to use its best efforts to market and sell CellSearch by, among other things, failing to deploy a sufficient sales force that was properly trained and had adequate incentives to “detail” the technology.
2. That Veridex breached its express contractual obligation to permit Immunicon to conduct an audit of Veridex’s books and records pursuant to § 3.6.3 of the DLS Agreement.
3. That Veridex breached its fiduciary duties of loyalty, good faith and candor, owed by it as Immunicon’s “agent.”
4. That Veridex and its parent company, J&J engaged in an illegal plan to limit the sale of Immunicon Products to provide an advantage to competitive products that Veridex or other J&J companies were developing, and to drive down Immunicon’s stock price so that J&J could purchase Immunicon and its products at a bargain basement price. This alleged illegal plan included a retaliatory campaign engaged in by Veridex to force Immunicon to fail, through covert communications with Immunicon shareholders and deliberate disruption of Immunicon’s planned financing. It also allegedly included a

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<sup>11</sup> While Immunicon’s Statement of Claim did not include a claim based upon common law fraud, in its Pre-Hearing Brief Immunicon suggested that a fraud had been perpetrated principally based upon knowingly false representations made by Roy N. Davis, Veridex negotiator, during pre-contract discussions. A claim not unlike that was made during Immunicon’s Opening Statement. No fraud claim, however, appears to be asserted in Immunicon’s Post-Hearing submissions.

plan to use Immunicon technology to boost its own competitive “GeneSearch” product.<sup>12</sup>

Veridex generally denied the allegations asserted in Immunicon’s Statement of Claim, and asserted various affirmative defenses and counterclaims. The counterclaims alleged Material Breaches of the DLS Agreement by Immunicon and a claim for tortious interference with prospective economic advantage. Veridex asserted as affirmative defenses that, *inter alia*, (i) Immunicon’s claims are barred by the doctrine of unclean hands; (ii) Immunicon’s claims are barred to the extent that they seek amounts or relate to categories of dispute or relief barred by the DLS Agreement (including consequential or special damages, punitive damages, attorneys’ fees, and costs of arbitration); (iii) the Arbitrator lacks jurisdiction over such of Immunicon’s claims as seek any form of specific or injunctive relief, or that seek consequential, incidental, indirect, punitive or special damages; and (iv) Immunicon failed to conform to the notice and cure provisions in the DLS Agreement and therefore brought its claims for Material Breach prematurely.

Veridex’s counterclaims were based upon the assertion that Immunicon had committed various Material Breaches of the DLS Agreement, including:

1. That Immunicon was chronically late in complying with its responsibilities under the DLS Agreement, while it failed to fulfill other duties altogether.
2. That Immunicon failed to produce a “fully automated” device, and failed to provide Veridex with the appropriate software to operate the device, both obligations that the DLS Agreement expressly imposed upon Immunicon.
3. That Immunicon failed to fulfill its obligations to develop products and conduct clinical trials to gain FDA approval for use of Immunicon Products for other types of cancers in accordance with the timeline set forth in the contract.

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<sup>12</sup> No claim in this form appears to have been pursued in Immunicon’s Post-Hearing submissions.

4. That Immunicon failed to maintain sufficient inventory of its products, in breach of § 6.11.1 of the DLS Agreement.
5. That despite these failures to perform on Immunicon's part, Veridex nevertheless exercised reasonable efforts to market and sell the Immunicon Products.
6. That Immunicon breached both Veridex's exclusive license to market and sell the Immunicon Products in the "Field" of cellular diagnostics and the covenant of good faith and fair dealing through its use of the Immunicon Products in its "Pharma Services" business.
7. That Immunicon tortiously interfered with Veridex's business prospects through Immunicon's "Pharma Services" business by approaching Veridex's prospective customers and offering to sell them substantially similar or identical products.

Immunicon essentially denied the allegations in the Veridex counterclaims.

Immunicon seeks as relief immediate termination of the DLS Agreement and all agency, distributor and licensee rights conferred on Veridex thereunder; compensatory and punitive damages and an equitable accounting of all monies received and profits taken by Veridex as agent, distributor and licensee under the DLS Agreement. It also seeks to have Veridex's counterclaims dismissed and for Veridex to be ordered to pay all of Immunicon's ICDR administrative fees and costs.

Shortly prior to the commencement of hearings, Veridex withdrew all of its claims for Material Breach except for two. What it preserved in its post-hearing briefing, however, was only its claim for breach by Immunicon of the exclusive license and its duty of good faith and fair dealing relating to the "Pharma Services" business and for an award dismissing all of Immunicon's claims and granting Veridex damages on its counterclaim and for specific performance of the DLS Agreement.

#### Immunicon's CTC Assay Technology

In the late 1990s Immunicon developed a technology in which small magnetic particles



are joined to antibodies that will only bind to cancer cells. The joined-together particles are contained within chemicals called "reagents" which are mixed with 7 1/2 milliliters of a human's blood sample. The antibodies and magnetic particles then bind to circulating tumor cells ("CTCs") in the blood sample. The blood sample is then analyzed which permits the CTCs to be separated from many other cells in the sample where they can be observed and counted by fluorescence microscopy. The technology was named "CellSearch" and will be generally referred to here as such. The components of CellSearch are CellSave Tubes, CellSearch Reagents, the CellTracks Auto Prep Instruments and the CellTracks Analyzer II Instruments.

#### The DLS Agreement

As CellSearch was being developed, Immunicon concluded that it might be necessary to form a relationship with a company with worldwide presence to sell and market its technology. It later began discussions with OCD which was a large marketing and distribution company in the field of the diagnosis of human disease. Following discussions with Roy N. Davis, then with OCD, Immunicon and OCD entered into the DLS Agreement as of August 17, 2000. The contract gave OCD a 20-year worldwide exclusive right to distribute and sell CellSearch.

Under the Agreement, Immunicon assumed the burden of conducting research and development leading to the commercialization of its technology and Veridex assumed the role of distributing and selling worldwide the products manufactured by Immunicon. Other salient parts of the DLS Agreement are summarized above.

#### FDA Clearance and the NEJM Article

By June, 29, 2004 the United States Food and Drug Administration, based upon the IMMC 01 study conducted by Immunicon, granted clearance to CellSearch for certain use in patients with metastatic breast cancer. Following the FDA clearance, in August 2004, the New

England Journal of Medicine ("NEJM"), a prestigious medical journal, published its findings on Immunicon's IMMC 01 study.

## I. THE BASIC DISPUTE

This dispute basically breaks down into three issues. First, whether under the Agreement Veridex owed Immunicon a duty in terms of its efforts to distribute and sell CellSearch. Second, assuming Veridex had a duty, whether it was satisfied. And in answering this second issue, a third and critical issue is raised, i.e. in light of the nature of CellSearch during the relevant time period and what it provided to users of the technology, whether Veridex's performance in distributing and selling CellSearch satisfied its obligations, express or implied, under the Agreement or, in fact, was the cause of CellSearch's lack of sales.

### A. Was Veridex Obligated to Use Its Reasonable Efforts

Immunicon asserts as a core issue in this proceeding that Veridex had an obligation to Immunicon to use its best efforts to promote and sell CellSearch, that Veridex was the exclusive worldwide licensee and sales agent for CellSearch, and that Immunicon, absent success by Veridex in achieving sales, had no way to recoup its investment or to be a financially viable company. It seeks compensatory damages in the sum of \$254.2 million.

Immunicon heavily relies upon the seminal case of Wood v. Lucy, Lady Duff Gordon, 222 N.Y. 88 (1917) (Cardozo, J.) to support its "best efforts" claim. There the court under a contract in which the exclusive licensee had undertaken no express obligation to sell the licensor's products, implied a promise by the licensee to use his reasonable efforts to do so. The holding of Wood has been consistently recognized in New York and elsewhere and applied, with exceptions, based upon individual factual distinctions.

Immunicon also relies upon Section 2-306 of the New York Uniform Commercial Code (“U.C.C.”) which imposes in exclusive dealing situations involving the sale of goods, a “best efforts” obligation on sellers and buyers “unless otherwise agreed.”

Veridex offers various arguments as to why the holding in Wood and the U.C.C. should not apply here. Immunicon has anticipated these arguments and the positions of the parties are summarized here.

1. The Agreement Does Not Obligate Veridex to Any Minimum Sales and Marketing Efforts

Veridex states that there is no provision of the Agreement that imposes any obligation upon it to deliver minimum sales volumes, requires it to meet any spending requirements, provides for the number of sales representatives who should be devoted to the promotion and sale of CellSearch or provides for how many representatives would be deployed. To the extent there are any obligations of Veridex under the Agreement relating to the distribution and sale of CellSearch, Veridex says they are in no way supportive of any express or implied obligation of the kind Immunicon seeks to impose.

Immunicon does not appear to challenge Veridex’s position with respect to the language of the Agreement and relies upon the implied obligation of the kind found in Wood and the U.C.C.

2. The Integration Clause Bars Any Implied Obligation

Veridex relies upon the broad integration clause as set forth in § 16.12 of the Agreement. That provision recites the desire of the parties for certainty with respect to their rights and remedies, that it represents the full extent of the legally enforceable undertakings between them and, perhaps significantly, expresses the parties’ agreement that neither have relied upon anything, including “implied” obligations, in entering into the Agreement.

Immunicon argues that § 1.2 of the Agreement expressly obligates Veridex to market and distribute CellSearch, while again obliquely conceding there is no provision of the Agreement expressly imposing any obligation as to how Veridex should do that. Immunicon also asserts that an integration clause cannot prevent the imposition of an obligation imposed by law.

3. The Availability of Milestone and Other Payments

Under the Agreement, Immunicon received an initial equity investment of approximately \$5 million from JJDC, a J&J entity, and an upfront payment of \$1.5 million. On top of these early injections of cash into Immunicon, the Agreement provided for “Milestone payments” which were payable by Veridex upon the successful completion of various steps under the Agreement. Veridex argues that because of all of these payments, totaling over time \$16.5 million, Immunicon was not left to look only to license fees earned upon CellSearch sales, but received significant cash infusions showing mutuality unlike the facts in Wood, so that reasonable “efforts” should not be implied – Immunicon was not at the mercy of Veridex’s sales efforts.

Immunicon argues that the combined \$16.5 million of payments by Veridex, or more specifically the \$1.5 million paid within three days of the effective date of the Agreement, was only a small fraction of the \$107 million Immunicon has spent developing CellSearch and that in the circumstances the implied duty of reasonable efforts should be applied.

4. Other Reasonable Best Efforts Provisions in the Agreement

Veridex points to other provisions of the Agreement where the parties in fact imposed upon each other specific reasonable efforts obligations as indicators of the parties’ intent to impose no such duty upon Veridex with respect to the promotion and sale of CellSearch, as to which the Agreement, as stated above, is silent.

Immunicon relies again upon § 1.2 of the Agreement which generally states that CellSearch would be marketed and distributed worldwide by Veridex and urges that this provision is an express obligation as to which a reasonable efforts obligation should be imposed under the principles enunciated in Wood and mandated by the U.C.C.

5. CellSearch Was Experimental and Undeveloped When the Agreement Was Signed

Veridex argues, relying upon the fact that CellSearch was “new-to-the-world” technology, “a work in progress” when the Agreement was signed, that only unproven developmental pre-clinical technology was being licensed and that much additional work was required, including regulatory approval before it could be marketed, so that no reasonable “efforts” obligation should be implied – too much remained to be done.

Immunicon distinguishes the single case upon which Veridex relies for its argument. It asserts that unlike that case, Immunicon did in fact fully develop its technology and secured regulatory approval at a cost of \$107 million and it would be unfair not to apply a reasonable “best efforts” obligation based upon Veridex’s obligations under § 1.2 of the Agreement to market and distribute CellSearch.

6. In the Negotiation of the Agreement Reasonable Diligence Was Excluded

Immunicon, in the negotiation of the Agreement, proposed a provision obligating Veridex to use “reasonable diligence” in the sale, marketing, distribution and servicing of CellSearch. Such a provision was not incorporated in the Agreement. Veridex argues that implying a reasonable efforts obligation in these circumstances would be wrong in that it would be implying an obligation that was specifically considered by the parties and rejected.

Immunicon’s response seeks to explain the rejection of the proposed “reasonable diligence” provision on the basis that Veridex’s rejection was not based upon its unwillingness in

the ordinary course to assume some burden of reasonableness, but rather upon the absence of any “comparable” product and that undertaking the burden of reasonable diligence in such circumstances would be unworkable.

7. Immunicon’s Public Filing Acknowledges No Reasonable “Best Efforts” Duty Was Intended By the Parties

Immunicon became a public company in 2004. In connection with selling its stock it included in its prospectus, which by law is required to be truthful, a provision in which it acknowledged that Veridex assumed very limited obligations in the promotion and sale of CellSearch and that such obligations did not require Veridex to meet any minimum levels of sales, marketing personnel or marketing expenditures.

Immunicon does not challenge the factual basis of Veridex’s argument except to repeat, as discussed above, that what it said in its prospectus does not modify Veridex’s obligations under the Agreement and the implied duties imposed by law under Wood and the U.C.C. to use its reasonable efforts.

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As shown here, and as more expansively set forth in their post-hearing submissions, the parties have laid out in great detail both sides of the issue of whether there should be imposed upon Veridex an obligation to make reasonable efforts to carry out its obligations under the Agreement as the exclusive worldwide licensee to promote and sell CellSearch. Having considered this issue, which could be determinative of the principal dispute in this Arbitration, and could also be important to the parties should the Agreement continue for the balance of its initial term of 20 years, the Arbitrator has concluded that Veridex assumed no express obligation to make reasonable efforts in promoting and selling CellSearch. However, Veridex did in fact have such a duty which should be implied here under all the facts.



A central reason for the Arbitrator's conclusion is that despite all of Veridex's arguments to the contrary, it would be fundamentally unfair and contrary to the core of the holding in Wood for Veridex to enter into an exclusive contract of the kind involved here and to have no obligation to carry out the core purpose of the contract -- to distribute and sell CellSearch.

Also, the Arbitrator is satisfied, despite the arguments made here by Veridex, that it was the intent of Veridex to act reasonably in carrying out the basic purpose of the Agreement. With no specific language in the Agreement laying out either general or specific parameters of the obligation Veridex assumed in terms of promoting and selling CellSearch, not to impose an obligation to act reasonably would be to leave one with a contract that would lack mutuality of obligation and that would not make common sense.

B. Did Veridex Satisfy its Duty

As noted above, the response to this inquiry cannot be answered in isolation. The answer is bound within the third issue. That issue in simple terms is whether taking into account all of the facts and circumstances, was the Veridex performance reasonable or, was it the cause of the lack of sales of the CellSearch technology. Before addressing the third issue we review here the positions of the parties with respect to Veridex's performance.

It is worth noting that Immunicon claims to have expended over \$100 million in commercializing CellSearch and that Veridex, through July 2007, claims it has spent \$70.2 million in its efforts to sell it. Clearly neither party has thus far found the relationship financially rewarding, although both appear to retain a reasonable expectation that the technology may prove out to be a significant breakthrough in cancer care.

Starting at the beginning, the contract Immunicon entered into in 2000 was with OCD. OCD is a large company with over a billion dollars in sales, many employees devoted to distributing and selling products and an established reputation in diagnostics. In October 2000

OCD formed Advanced Diagnostic Systems ("ADS") as a business group within OCD. ADS was given the job of dealing with the Immunicon relationship. At its outset it had limited resources in terms of personnel and finances and no experience in the marketplace in which CellSearch would be sold. The intention was that ADS would gain access to the market with the assistance of other J&J entities. ADS, as part of OCD, continued its involvement as the Immunicon direct servicing entity until late 2003 when OCD's rights and obligations under the Agreement were assigned to Veridex.

Veridex itself was a "start-up" company and while one of the core criticisms in this proceeding of the performance of Veridex was its lack of people to go out and sell the Immunicon technology, it appears that the intent of OCD at the outset, with the knowledge and approval of Immunicon, was to create a new entity devoted in large part to selling the Immunicon technology with OCD's help. What is clear, however, is that Immunicon agreed to OCD's right to assign its rights and obligations under the Agreement to Veridex, an OCD "Affiliate."

It is appropriate to state here in assessing Veridex's performance that it is no answer, as Veridex suggests, that how it distributed and sold CellSearch was a matter within its total discretion as a business judgment. While discretion must to some degree lie within the judgment of the party who assumes a duty under a contract which provides no specificity in terms of the obligations to be performed, as is the case here, such discretion must be exercised reasonably and not without boundaries. This leads us back to the application of the reasonableness standard, which is the standard adopted by the Arbitrator in this proceeding against which Veridex's performance must be judged.

In its submissions, Immunicon has spelled out in great detail the evidence upon which it relies to prove that Veridex totally failed to reasonably perform its obligations under the Agreement. An attempt to summarize that evidence is made here. Veridex has responded and in due course that response will be summarized as well.

1. ADS which was given the responsibility for working with Immunicon, was a brand new entity and had limited resources, limited personnel and no experience in the marketplace where CellSearch would have to be sold. While ADS would work with OCD or other J&J affiliates, such cooperation never happened to a meaningful extent.

2. Efforts by OCD to harness the expertise of OBI, a J&J division dedicated to oncology, to present a collaborative approach to the oncology community, were not successful. During the period prior to the assignment of the Agreement to Veridex, Immunicon from time to time was advised that OCD was developing the competencies of OBI in support of Immunicon's technology although nothing of any significance was ever forthcoming.

3. While OCD's plan of "pull marketing" using other J&J entities for the sale of Immunicon's technology after its launch was discussed, no such "pull marketing" was ever brought to bear.

4. A later plan to use the sales force of Tibotec, a division of OBI, to gain access to oncologists also proved to be a failure.

5. At a meeting with the Immunicon Board on March 20, 2003 which came about as a result of Immunicon's concern about the progress being made to prepare for the launch of CellSearch, the Board was told that J&J was interested, supportive and was going to pursue a very aggressive marketing program to which it was committed in terms of producing a successful commercial outcome.

6. At this Board meeting, J&J was described as being uniquely positioned to serve the oncology community through its affiliated entities and in particular OBI, and that ADS was a major J&J strategic priority.

7. The representations made to the Immunicon Board were consistent with the pre-contract representations concerning OCD's intention to aggressively detail CellSearch to oncologists and that such efforts would be given priority.

8. The statements made to the Immunicon Board on March 20, 2003 were false.

9. Nothing of substance was accomplished to prepare for the launch of CellSearch between the time the contract was entered into in August 2000 and the initial FDA clearance in January 2004.

10. Veridex, which replaced OCD in late 2003, was a startup company with no selling organization and no links to the medical community. It had no sales or marketing competence or experience in launching products to the medical profession.

11. Veridex also had severe financial limitations in terms of its budget and again, as with ADS, was subject to reliance upon other J&J entities to promote the Immunicon technology.

12. Although Veridex knew prior to the launch of CellSearch in late 2004 that the creation of demand for the technology would require direct access to oncologists, it had no capacity on its own to "detail" to the oncologist community or to follow-up with oncologists in pursuit of sales.

13. Efforts to harness the sales force and experience of OBI and/or Tibotec were a failure. The plan for access to 80 trained representatives of Tibotec to sell CellSearch to oncologists never happened because of an alleged conflict with another product the Tibotec representatives were selling and because selling CellSearch would negatively impact the income of the Tibotec representatives. The net result is that Tibotec withdrew from any collaboration to sell CellSearch.

14. The withdrawal of Tibotec presented Veridex with a problem in penetrating the market.

15. The handful of Territory Managers which represented the totality of Veridex's sales force was inadequate and was focused on selling the CellSearch Analyzer equipment.

16. Without assistance from the Tibotec or OBI sales forces, the Veridex Territory Managers were grossly insufficient in number to market CellSearch.

17. Veridex's efforts, after Tibotec withdrew, in attempting to utilize OBI representatives produced no meaningful results in terms of CellSearch sales. At best a limited "pilot program" was launched with OBI in 2005.

18. As late as 2006 Veridex was still searching for a marketing strategy for CellSearch.

19. Renewed efforts in early 2007 utilizing OBI personnel from its "Business Solutions Group" to work with CellSearch provided modest results.

20. In the final analysis neither OCD nor Veridex had the capacity to secure any meaningful help from any other J&J affiliated entity in their efforts to sell CellSearch and in particular to provide the required number of personnel to detail the technology to the oncology market.

21. The Veridex website was totally ineffective as a marketing tool.

22. Veridex rejected a direct-to-patient advertising campaign, which could have stimulated interest by oncologists.

23. Veridex failed to create an appropriate Medical Affairs Department which impeded adoption of the CellSearch technology.

24. Veridex's argument that calling on oncologists is not essential to successfully market a product like CellSearch cannot be supported.

On its face, this is not a frivolous list of shortcomings in Veridex's performance. Also, what must be added to it is evidence which is relied upon by Immunicon which shows the contemporaneous acknowledgment by Veridex personnel of these shortcomings and their frustration, in terms of getting a more effective and efficient organization in place to sell CellSearch.

Veridex's response to the Immunicon arguments on the inadequacy of Veridex's performance and the evidence upon which it relies, is "like two ships passing in the night." The basic departure arises from Veridex seeing its performance as a "controlled launch" rather than an unsuccessful effort to get help from J&J Affiliates to get a strong selling effort planned and set in motion. It relies to some degree upon the shortcomings in Immunicon's performance, but more forcefully on the correctness of its plan to launch the sale of CellSearch by pursuing opportunities through major cancer centers, oncologists who were "thought leaders," "key opinion leaders," by vigorous participation in national meetings of oncology organizations and the placement of the CellSearch instrumentation at laboratories which would encourage the testing of patients with metastatic breast cancer. Its position, equal in its detail to that of Immunicon, is summarized here.

1. The CellTracks Analyzer was intended to be launched once FDA regulatory approval was given. Immunicon could not meet that schedule and deliver the instruments. The problem continued into 2004 when critical technical errors were found in the equipment.

2. To meet the Analyzer problem Immunicon proposed using what was called the CellSpotter device for research use only and introducing the Analyzer when it was ready for sale. The delay was caused by Immunicon which could not overcome its technical problems. These

delays placed constraints on Veridex's marketing efforts and the placement of the instruments with "key opinion leaders."

3. Later the CellTracks Analyzer II units shipped in June of 2005 failed inspection and the FDA did not clear the software system for the Analyzer II until March 2006; it was further delayed until July 2007. Immunicon was responsible for these delays.

4. At various times Immunicon failed to provide accurate data for regular submissions to the FDA or provided inaccurate data; such was the case with respect to submissions for metastatic lung cancer and adjuvant lung, breast, colorectal and prostate cancer.

5. Immunicon did not satisfy in a timely manner any of the Milestones in the Agreement and all had to be revised.

6. Prior to the completion of Immunicon's IMMC 01 study, Veridex conducted market research, developed a pricing strategy for products and a reimbursement strategy to be used by patients, each of which was essential to a successful launch for what was "new-to-the-world" technology.

7. The parties agreed to a "controlled roll-out to key strategic accounts" in March 2003. Because of Immunicon's technical problems the "controlled roll-out" did not occur until late 2004.

8. Immunicon's own expert at the hearings agreed that when marketing to oncologists, the size of the sales force did not matter because oncologists are conservative, base their clinical decisions on data from medical journals and not sales representatives and are most influenced by the experience of their peers or key opinion leaders.

9. Because it was "new-to-the-world" technology a "controlled launch" was required and was agreed to with a focus on key opinion leaders, national cancer centers and hospitals that treated large numbers of breast cancer patients which could be encouraged to adopt CellSearch as part of their routine practices.

10. Getting prominent oncologists to speak at national meetings was important to the "controlled launch" as was the encouragement of oncologists to publish the results of the use of the technology. Veridex did that. Sales representatives alone could not accomplish these objectives and it would have been a mistake to promote CellSearch primarily with large numbers of sales representatives.

11. An FDA clearance alone is not a factor in getting a diagnostic test included in treatment guidelines, because the FDA clearance of such a test does not include an evaluation of the clinical utility of the test.

12. The "controlled launch" was begun in collaboration with Immunicon in early 2004 with assistance from the sales force from OBI; OBI had experience in oncology and sales representatives with access to oncologists.



13. Veridex had a large presence at the May 2004 ASCO meeting.

14. The NEJM publication of the IMMC 01 study done by Immunicon created great awareness among oncologists about CellSearch.

15. The national launch of CellSearch in December 2004 was in conjunction with the San Antonio Breast Cancer Symposium ("SABCS"); this is a "premier" international breast cancer meeting. At the meeting Veridex sponsored a medical education program focusing on CellSearch which was chaired by two of the investigators of the NEJM article.

16. Veridex reached an agreement with Quest Diagnostics in 2004 for it to become the exclusive national reference laboratory for CellSearch. This was a beneficial relationship and while it did not produce all the results hoped for by Veridex, it created a good working relationship with Quest, which became the largest customer in the world for CellSearch and accounted for a significant percentage of reagent sales in 2006 and 2007.

17. Sales representatives from Tibotec also received training from Veridex in the summer of 2004 about CellSearch and assisted throughout 2004 in developing leads and an awareness of CellSearch among oncologists.

18. When Tibotec, for conflict reasons could no longer provide assistance in the sale of CellSearch, Veridex began training OBI representatives in June 2005 to help create a pilot program in several regions of the country. OBI representatives have worked successfully with Veridex representatives to provide detailing to oncologists regarding CellSearch.

19. Territories in which the Veridex Territory Managers function were created to insure that each Veridex representative could contact significant metastatic breast cancer oncologists and make follow-up contacts.

20. Veridex had a significant presence at the ASCO 2005 meeting where more than 500 oncologists from around the country obtained information about CellSearch. At the same meeting 3,000 oncologists attended a presentation concerning the IMMC 01 data given by a respected doctor who was one of the lead investigators of the NEJM article, for which he received a standing ovation.

21. Veridex increased its commitment in resources and manpower to CellSearch in 2006 and 2007.

22. At the 2006 ASCO meeting attended by hundreds of physicians from around the world, detailed information about CellSearch was distributed and Immunicon, which had personnel present, observed the heavy activity at the Veridex booth which was observed to be selling CellSearch "big time."

23. The value of direct-to-patient advertising is under serious question by oncologists and as testified to by Immunicon's expert, direct-to-patient advertising should be avoided until a

significant level of acceptance of the product or technology has been reached by physicians in the field.

24. There was no testimony in the proceeding that a majority of oncologists today has confidence in CellSearch.

The Veridex demonstration of the reasonableness of its performance under the Agreement is itself persuasive.

It is obvious, however, that the parties are simply looking at the issue of the Veridex performance through two different lenses. Immunicon basically says Veridex from virtually “day one” never had an effective plan in place to market CellSearch, either alone or with the help of other J&J entities. In particular it argues that Veridex never had the capacity to penetrate the broad potential market – the oncologists who are the ultimate users of CellSearch in the clinical care of their patients. Veridex on the other hand, says that for this “new-to-the-world” technology, the “controlled launch” which it used was the correct way to try to achieve adoption of the technology and that “detailing” to thousands of oncologists would be ineffective. Veridex also says getting the leaders of the oncology community on-board and building an acceptance and adoption of the technology with them was the sound way to proceed. Veridex urges that this approach could then bring adoption from the larger oncology community and ultimately have the use of CellSearch become part of “the standard of care.”

As pointed out above, to determine the reasonableness of Veridex’s performance requires consideration of what CellSearch as a new technology had to offer the oncology community in the clinical treatment of patients with metastatic breast cancer and to determine whether it was the limits of the technology or the way Veridex carried out its distribution and sales obligation that caused the lack of success in getting CellSearch sold and more broadly used.

It is to that issue to which we now turn.

C. What Caused the Lack of Success of CellSearch; Veridex's Shortcomings or the Limits of the Technology

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In January 2004 the FDA granted clearance for *in vitro* diagnostic use of the main components of CellSearch. The Immunicon IMMC 01 study was the basis for the clearance. The intended use of CellSearch as cleared was for the counting of CTCs in whole blood of patients who had metastatic breast cancer. A CTC count of 5 or more per 7.5 millimeters of blood would be predictive of shorter progression free survival and overall survival.

On the other hand, if the CTC count was more than 5 at the beginning of the therapy administered to such a patient and soon thereafter was found to be less than 5 it could suggest that the therapy was working. The ability to make such prediction far earlier in the treatment of a patient than with other predictors of disease progression then in use was significant. This finding was later described in an editorial accompanying the NEJM August 2004 article as a major finding and an important step toward decisions about the individualized treatment of patients with metastatic disease.

Dr. Daniel Silver, a well qualified doctor at the Dana-Farber Cancer Institute, a leading cancer center, called as an expert witness for Immunicon, described the conclusions of the IMMC 01 study:

This study showed that in patients with metastatic breast cancer who are embarking on a new therapy, either the first therapy or the second, third, or fourth therapy for that cancer, a single determination of the number of circulating tumor cells in 7.5 milliliters of blood [was] sufficient to confer prognosis.

Patients who have equal to or greater than five cells per 7 ½ milliliters of blood fare poorly both in terms of progression free survival, that is, whether their tumor is growing either in the sites it already is in or in new sites, or in overall survival, that is, the time to death. Whereas, patients who have between zero and four cells per 7 ½ milliliters of blood, between zero and four cells per 7 ½ milliliters of blood, do much better in terms of either progression free survival or overall survival.

Furthermore, the study takes this one step farther. If you look three to four weeks after the initiation of a new round of therapy and take another determination of the number of circulating tumor cells per 7 ½ milliliters of blood, if the patient at that point has less than five cells per 7 ½ milliliters of blood, that is a good prognostic indication. In fact, if the patient had more than five -- more than four at the beginning and then had less than five three to four weeks after the onset of a new therapy, the patient then has the same prognosis as a patient who had less than five to begin with. So it also predicts response to therapy.

The FDA clearance and the NEJM article produced great enthusiasm at Immunicon and Veridex concerning CellSearch and its prospects. With these positive developments the issue in terms of the commercialization of CellSearch rested on the answer to the question of whether oncologists would adopt the technology, which turned on its usefulness in a clinical setting. As was agreed to at the hearings, oncologists are conservative by training in approaching new technologies in the care of their patients. Immunicon's case is built upon the general proposition that Veridex's failure to distribute and market CellSearch in a reasonable manner to the oncology community was the cause of its lack of success. Veridex on the other hand says its performance was reasonable in light of the shortcomings in the technology to persuade oncologists to adopt CellSearch in a clinical setting.

While it requires a jump ahead in the chronology, it seems to be of importance to this issue to understand the reasons for the lack of success in the marketing of CellSearch, that the abstract of ASCO,<sup>13</sup> published in October 2007, be considered. The "Special Article," which is

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<sup>13</sup> The "American Society of Clinical Oncology" is a non-profit organization founded in 1964 with overarching goals of improving cancer care and prevention and ensuring that all patients with cancer receive care of the highest quality. More than 25,000 oncology practitioners belong to ASCO, representing all oncology disciplines and subspecialties. ASCO is committed to advancing the education of oncologists and other oncology professionals, to advocating for policies that provide access to high-quality cancer care, and to supporting the clinical trials system and the need for increased clinical and

an update of ASCO's Guidelines, is entitled "American Society of Clinical Oncology 2007 Update of Recommendations for the Use of Tumor Markers in Breast Cancer." The Article states it was reviewed not only by the Update Committee, but also ASCO's Health Services Committee and its Board of Directors. It states in relevant part as follows with respect to CTCs as Markers for breast cancer:

2007 recommendation for circulating tumor cell assays. The measurement of circulating tumor cells (CTCs) should not be used to make the diagnosis of breast cancer or to influence any treatment decisions in patients with breast cancer. Similarly, the use of the recently US Food and Drug Administration-cleared test for CTCs (CellSearch Assay; Veridex, Warren, NJ) in patients with metastatic breast cancer cannot be recommended until additional validation confirms the clinical value of this test.

\* \* \*

However, there are no data yet generated to prove that the use of this CTC test leads to a longer survival time or improved quality of life for the patient with metastatic breast cancer. In this regard, the SWOG<sup>14</sup> and the Breast Cancer Intergroup of North America recently have initiated a prospective trial in which patients with metastatic breast cancer who have an elevated CTC after one cycle of first-line chemotherapy will be randomly assigned to either remaining on that therapy until clinical and/or radiographic evidence signals progression, or switching therapy at that time point to a different chemotherapeutic agent.

While the Article was published almost three years after the launch of CellSearch, it appears directly to support the Veridex argument that a principal reason CellSearch has not been

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translational research. It has been described as the "premier society" in the field of oncology.

<sup>14</sup> Southwest Oncology Group ("SWOG") is one of the largest and most respected cancer clinical trials cooperative groups in the United States. It is funded by research grants from the National Cancer Institute, part of the National Institutes of Health and conducts clinical trials with respect to the prevention and treatment of cancer and to improve the quality of life for cancer survivors. SWOG's network of more than 5,000 physician-researchers practice at nearly 500 institutions, which includes 18 National Cancer Institute-designated cancer centers. SWOG has a study in progress dealing in general with the issue of whether CellSearch can be used as a predictor of the effectiveness of therapy in breast cancer patients. The results of this study may not be available until 2011.

adopted by oncologists is the absence of data to prove that its use will provide a meaningful benefit to patients in a clinical setting.

The only challenge in this proceeding to the ASCO statements was offered by Immunicon through the testimony of Dr. Silver, its sole oncologist expert. It is worth noting that Dr. Silver only recently learned of CellSearch and had not used it with any of his patients because he felt it inappropriate to do so only after he was retained as Immunicon's expert. While that explanation is not unreasonable, it appears the only challenge he offers to the ASCO Guidelines as to CellSearch is that ASCO "is holding CellSearch to a very high standard" and that the oncologists responsible for the Article, who he acknowledges are associated with institutions of significance in the oncology field, are being "too cautious." He knows of no other oncologist who holds his opinion.

It perhaps should be noted here that Immunicon called no other oncology expert. It is also notable that the editorial that accompanied the NEJM article published in August 2004 entitled "Circulating Tumor Cells in Metastatic Breast Cancer – Toward Individualized Treatment," along with spelling out the positive aspects of the CellSearch technology, stated:

Second, a cautionary note is warranted with respect to uncritical, immediate adoption of this assay for routine use and is in agreement with the authors' own opinion, as outlined in their careful discussion of the results. We still need to know, for example, whether any change in the treatment based on the number of circulating tumor cells alone will translate into a benefit in progression-free survival. The current findings clearly encourage such studies. Nevertheless, the already noticeable improvements are in themselves sufficient to allow us to speculate that this assay will soon realize its potential to change the standard of care for patients with metastatic breast cancer.

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Taken together, the article by Cristofanilli et al. and the studies it is likely to stimulate in the near future may substantially affect our current understanding of breast cancer and of the standards and practice of decisions about treatment not only in palliative care but also in adjuvant care for patients with this disease.



(emphasis added).

It is also not unfair to conclude therefore that even prior to launch in December 2004 that there were significant reservations concerning the immediate adoption of CellSearch for routine use and that additional studies appeared to be required to realize the full potential of the CellSearch technology.

Indeed as early as 2001, a study done by NFO Migliara/Kaplan<sup>15</sup> concluded that “adoption/acceptance of [CellSearch] remains to be determined by the outcome of clinical studies documenting the performance and value of this new test” and that “great care” was required in testing that went beyond that required for regulatory approval to address the “clinical ability” of the technology.

Again, before launch, in a report by Advanced Diagnostic Systems issued in June 2003, reflecting the professional views of a sample of oncologists to determine the strengths and weaknesses of the CellSearch concept, its clinical applications, possible future opportunities and factors influencing adoption of new diagnostic tests, the “data and validation needs” of CellSearch were described as:

Acceptance of concept is dependant on obtaining more data and validation, including larger base sizes (in the thousands of subjects).

Evidence-based medicine defines how they practice.

The test is perceived as not ready for prime-time. It will take a number of years before they use these tests in their practices because more data is necessary to validate the test and develop the correlations. (emphasis added).

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<sup>15</sup> NFO Migliara/Kaplan was a company that focused on market research for medical, laboratory and technical services, as well as diagnostics products, in the healthcare and pharmaceutical industries.

Further, in a study in late 2005, almost one year after launch, McKinsey and Company, a worldwide consulting firm, provided its reason for the lack of success in the adoption of CellSearch as follows:

The primary reason for slow growth is oncologists questioning the novelty of the test's claim. Oncologists require prospective clinical data, which shows that a change in therapy after 4 weeks, based on a circulating tumor cell assay, will improve a patient's outcome. Veridex's BRAT study, estimated to be finalized in 2006-2007, is aiming to address this exact need. (emphasis added).

In another study by GfK Market Measures<sup>16</sup> in November 2005, it concluded that oncologists using CellSearch need more studies/data, specifically related to the test's role in treatment decisions, before establishing a baseline test with it.

The lack of more data before adoption by oncologists was a need repeatedly expressed and acknowledged by and between the parties to the Agreement and by others.

Dr. John Park,<sup>17</sup> a well-qualified oncologist, was called as an expert witness by Veridex. He testified as to why CellSearch has not been a commercial success and why it is not widely used by oncologists:

Right. I think it relates to CellSearch. In spite of this, I mean, you know, I'm in this field, I believe CellSearch is a very good technology. I believe that it has quite a lot of potential in oncology and in cancer research, but I would say the consensus opinion among oncologists generally, and particularly among the academic community and the, let's say, expert opinion within oncology, has been uniformly that the data for CellSearch have not reached the critical mass nor the threshold to convince everyone that this should be adopted routinely as a clinical tool.

<sup>16</sup> GfK Market Measures was a market research company which conducted an e-mail survey of oncologists to determine how the profession was using CellSearch and to identify the unmet needs of those oncologists using the technology.

<sup>17</sup> Immunicon in challenging Dr. Park's direct testimony devoted a large part of its cross-examination in an effort to portray Dr. Park as having a bias in favor of Veridex. While the cross-examination was entirely proper it did not provide a basis upon which his testimony, unchallenged by any oncologist called by Immunicon who has used CellSearch, could be held to be other than entirely credible.

I think the threshold has been reached that it provides useful accurate information, although not everyone would agree. I certainly believe that, and I think many people would view that as having been shown. But whether it, using this in the practice of medicine actually will improve the outcome for the patient, which is a particularly important thing for practicing oncologists to know, how to use this to actually better the outcome for the patient, that has not been conclusively shown.

And so without that key piece, that has led the various consensus organizations that develop these views to uniformly say that the test is not ready to be adopted routinely in clinical practice.

He also explained the important leadership role of "thought leaders," "key opinion leaders," the academic community (in which Dr. Park plays a lead role) and major cancer centers in providing a basis upon which oncologists in local communities can rely in adopting new technology and why CellSearch has not been adopted.

Okay. Again, I think the key thing is that we don't know if using this information in the practice of medicine will make for a better outcome for the patient, and it's a new technology, it's a new idea for testing which I think speaks to the potential upside of it, but particularly for the practicing oncologist, the oncologist in the community where most of oncology care is delivered, they particularly look to sort of this expert opinion guidance about this topic.

And again, the expert opinion is what I've tried to state: That [it is] promising technology, informative, but not yet proven that it improves what happens to patients ultimately.

Dr. Park also testified that the CellSearch data alone does not provide a basis for an oncologist to change therapy, that the FDA clearance of CellSearch does not provide value to the clinician as to how it should be used with patients and that for the large number of patients with metastatic breast cancer, even those with aggressive disease, who show "zero" CTCs, the CellSearch test provides little help.

Veridex called Philip Perez as a witness.<sup>18</sup> He is a Territory Manager with Veridex. He started with Veridex in October 2004 just prior to the national launch of CellSearch. He was assigned to a large territory in the southeast United States consisting of part or all of six states. There were 75 breast cancer “specialists” in his territory, several national cancer centers and 20-25 hospitals treating many cancer patients; he had about 125 targeted key accounts in his territory. He only sold CellSearch.

In his three years selling CellSearch, including at trade shows, he has seen hundreds of oncologists and sought to sell them CellSearch. The common response he has received is:

This sounds great. There’s not enough data. This is not ready for prime time use. Come back to us when you have SWOG.” (emphasis added).

Perez explained what he saw would be required to achieve widespread adoption by oncologists:

To get widespread adoption and get the majority of oncologists using it on the majority of patients, we need either that or we need regional experts in the field, like the ones we’re trying to get, that say they use the test and this is how they use it. Without the data, that might help, without the data published, or ASCO to make a recommendation and say we recommend using CellSearch and this is the way to use it.

Another issue CellSearch faced was the determination by Aetna and Cigna, two leading health insurers, indicating they would not reimburse for CellSearch tests. Cigna’s coverage position was stated as:

The application of this technology has not been proven to affect outcomes in patients with metastatic cancer. There are no conclusive data to indicate that knowledge of this prognostic factor can be used to alter the therapy that is offered to patients and improve outcomes. While this testing may have potential for use in patient monitoring, there is currently insufficient evidence to determine the effectiveness of this technology as a marker of disease progression. Additionally, no head-to-head trials have demonstrated that this technology is equal to or better than any existing tumor markers in its efficacy and clinical utility. This

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<sup>18</sup> Perez’s testimony cannot be rejected as “anecdotal.” He is the only party witness who has provided specific testimony with experience directly dealing with oncologists “in the field” in a significant territory and relating their reasons for not adopting CellSearch.

technology has not been demonstrated to affect overall health outcomes for patients with metastatic cancer and is therefore considered experimental, investigational and unproven.

Immunicon itself observed in its Long Range Plan for 2005-2010 the unfortunate slow rates of adoption for “new-to-the-world” technologies like CellSearch:

New products must simultaneously have compelling clinical data associated with improved outcomes and reasonable pricing in absolute terms and must ideally displace the cost of existing modalities. Unfortunately, further compounding the challenges for medical products is relatively slow rates of adoption for innovative new medical technologies and the time and effort to establish attractive reimbursement.

Based upon the above evidence and taking fully into account the evidence introduced by Immunicon, the Arbitrator concludes as follows:

1. The performance by Veridex in distributing and selling CellSearch under the Agreement was reasonable. This conclusion has been reached on the basis that oncologists have not been persuaded to adopt the technology because it does not yet offer sufficient supporting data or benefit to patients with metastatic breast cancer who are being treated in a clinical setting.
2. The procedure for a launch of this “new-to-the-world” technology by Veridex was reasonable. For such technology, initially persuading the leaders of the oncology community to adopt CellSearch was a reasonable way to introduce this new product and try to secure its adoption. Without this groundwork with oncology leaders and success in convincing them to use CellSearch as part of their regular clinical practice in treating patients with metastatic breast cancer, there would be little hope in persuading the broader oncology community of the benefits of CellSearch. Without acceptance by oncology leaders, an effort to marshal large numbers of “detail” people to sell the technology would not be appropriate.
3. The lack of sales of CellSearch and the inability to secure the adoption of CellSearch by the general oncological community was caused not by Veridex’s failure to make

reasonable efforts to do so, but by lack of data and the current technological limits of CellSearch resulting in oncologists being unable to effectively use it with patients in a clinical setting

4. In its pre and post-hearing submissions and at the hearings, Immunicon sought to establish that to the extent CellSearch did not secure commercial success in persuading oncologists to adopt its technology in the clinical treatment of patients, because of the lack of additional supporting data, that failure was the responsibility of Veridex; that Veridex did not fulfill its obligation to conduct post-marketing studies. The Arbitrator rejects this argument for several reasons.

First, the Agreement reflects no obligation of Veridex to do such studies. Unlike the issue of whether an implied duty should be imposed upon Veridex to act reasonably in the distribution and sale of CellSearch, which the Arbitrator has found to be appropriate, no such duty can be found with respect to post-marketing studies. Indeed an effort to include such a provision in the Agreement was rejected by Veridex. The holding of Wood would not apply, nor would the U.C.C. in these circumstances nor does Immunicon suggest so. Imposing such a duty would be unreasonable and in effect would place a burden on Veridex to take steps to make CellSearch acceptable to oncologists in the clinical care of their patients through studies that would make it so. No such burden can be implied.

Second, Immunicon in its detailed Statement of Claim dated May 31, 2007, makes no mention of any claim against Veridex based upon the failure to secure greater commercial success for CellSearch because of Veridex's failure to perform post-marketing studies. While a claim should not limit the proof that may be offered as a proceeding progresses through hearings, provided the other side is given notice and a fair opportunity to respond, as was the case here, the forceful assertion of this issue by Immunicon seems to have been presented only after the ASCO



2007 Guidelines update was issued citing the shortcoming of data supporting the clinical value of CellSearch. The need for significant supporting data to lead to adoption of CellSearch by oncologists was well-known to both parties when the claim was filed and for Immunicon not to have raised this issue in its Statement of Claim casts significant doubt upon its merit.

Third, we see no exchanges between the parties in which any claim is asserted of a Material Breach of the Agreement by Veridex for not doing post-marketing studies. For example, had this issue been important, one would expect it to be included in the "Talking Points" prepared by Immunicon in March 2006 to persuade Veridex to reform the Agreement by specific amendment[s] to achieve better success for CellSearch. Post-marketing is not there. Nor is there any mention of such a failure in the detailed memorandum by two independent directors of Immunicon to the full Board of the company, who met with a senior J&J person in late 2005. Rather, the memorandum reports on the confirmation given by J&J of a strong commitment to the Immunicon technology. To the extent that there is any indication with respect to gaining more patient data generation and providing funds for clinical trials relative to existing and new indications, the memorandum is cast in terms of getting J&J's financial "help," for which Immunicon would have to give a "quid pro quo." All hardly suggesting any obligation to do post-marketing studies.

Fourth, Immunicon's marketing expert, in a detailed initial report of the failure of Veridex to fulfill its obligations to Immunicon, makes no statement concerning its failure to conduct post-marketing studies. However, the expert's rebuttal report, which appears to have been filed after the ASCO 2007 Guidelines, contains a segment devoted to Veridex's failure to devote enough efforts to post-marketing studies. If such studies were such an important reason for the failure of CellSearch to gain adoption, it seems it should have found its way into the initial report.

5. In arriving at these conclusions we do not mean to suggest that the performance by OCD or Veridex in planning and executing a broader approach to the general oncology community to sell CellSearch, both before and after launch in December 2004, was satisfactory. Immunicon has made a showing from which it argues the performance was in fact “shabby” and was seen as such internally at OCD and Veridex as it was happening. Assuming that to be the case, the issue as seen by the Arbitrator was whether it was that performance that caused the lack of success in persuading clinical oncologists to use and then adopt the technology as part of a standard of care, or, whether the lack of success was caused by the inherent limitations of the technology, which despite a “controlled launch,” was unable to show enough data to establish the clinical value to those treating patients.

In the face of ASCO’s 2007 Guidelines update, the limitations of the technology recognized in the NEJM 2004 Article and the accompanying editorial, the various written commentary, both before and after the CellSearch launch, the written exchanges between the parties and with others, the absence of any testimony from any oncologists who have adopted the technology in a clinical setting and taking into account the conservative mind-set of the oncology community concerning new technology, the Arbitrator was left with only one conclusion – the current limitations of the technology caused the failure of CellSearch to achieve significant commercial success.

In resolving this issue on the basis that the technology did not offer enough to result in commercial success – at this time – the Arbitrator is of the view that the CellSearch technology in being able to segregate and count CTCs from blood of humans, is in fact a breakthrough which promises to be a technology adopted broadly as part of a standard of care in the treatment of the victims of cancer or provide a foundation for other significant developments in cancer

treatment.

## **II. DID VERIDEX OWE IMMUNICON A FIDUCIARY DUTY**

§ 16.14 of the Agreement is captioned “No Agency.” It acknowledges the Sales Agency relationship created by § 6.4.1(a) and specifically eliminates from the relationship the creation of a joint venture, an association, a partnership or any other agency relationship. It defines the relationship of the parties as independent contractors.

The Agreement and the history of its negotiation, as well as the manner in which the parties dealt with each other during performance, clearly show that the Agreement created a pure commercial relationship between two sophisticated entities which was negotiated and performed at arms-length.

There is no basis upon which Veridex could be held to owe Immunicon a fiduciary duty. Certainly the Sales Agency provision did not create such a basis nor can it be found anywhere within the Agreement.

## **III. DID VERIDEX MATERIALLY BREACH THE DLS AGREEMENT BY REFUSING TO COMPLY WITH ITS AUDIT OBLIGATIONS**

Immunicon claims that Veridex committed a Material Breach of § 3.6.3 of the DLS Agreement by refusing to supply Immunicon with a meaningful audit of its books and records. Immunicon states that on April 30, 2007 it sought, in writing, the right to conduct an audit of Veridex’s books and records “to ensure compliance with the provisions of [the] Agreement.” Veridex on May 11, 2007 replied and agreed to give Immunicon access to some of the materials requested in its audit demand letter, but refused to make available documents and promotional materials for Cellular Analysis Products, because “there are no contractual obligations relating to the promotion of . . . products [other than Cellular Analysis Systems].” Veridex also refused to provide access to documents from other J&J entities. Thereafter on May 21, 2007, claiming that

Veridex had “defeated the purpose of the audit” by limiting the documents it would make available, Immunicon cancelled the audit and told Veridex it would “explore other options available to [it] under the Agreement.” Three days later Immunicon initiated this Arbitration.

Veridex argues that it only blocked access to documents to which Immunicon was not otherwise entitled. As evidence that Immunicon was not entitled to these documents, Veridex cites the fact that the Arbitrator denied Immunicon’s motion to compel production of the very same documents that Immunicon sought from other J&J entities as part of its audit. Veridex also argues that Immunicon’s claim for Material Breach based on its allegation that Veridex refused to comply with Immunicon’s audit rights is not properly before the Arbitrator because Immunicon failed to comply with the explicit notice and cure provisions contained in § 13.6 of the Agreement. That provision requires the party alleging breach by the other to provide notice of Material Breach, which triggers a 90 day period during which time the party alleged to have breached the Agreement can cure.

Immunicon argues, in response, that the notice and cure provisions of the contract cannot protect Veridex from having repudiated its obligation under the DLS Agreement. It further argues that it complied with the notice and cure provisions because it notified Veridex on May 21, 2007 that it was dissatisfied with Veridex’s response to its audit demand, and more than 90 days have passed since that time and Veridex has made no attempt to cure.

First, Veridex cannot be treated as having breached the DLS Agreement for failing to provide access to documents in the possession of other J&J entities, since the Arbitrator determined that they need not be provided. Second, Immunicon’s letter of May 21, 2007 cannot fairly be read to be notice of Material Breach of the type contemplated by § 13.6 of the Agreement. It does not advise Veridex that it intended to treat its refusal to provide access to

certain documents as a Material Breach of the DLS Agreement, and it does not communicate any intent that the 90 day cure period begin to run. As such, the Arbitrator finds that Immunicon's claim that Veridex committed a Material Breach of the Agreement by refusing to permit an audit is denied and that claim is dismissed with prejudice.

#### **IV. VERIDEX'S COUNTERCLAIM – "PHARMA SERVICES"**

Veridex claims that Immunicon violated the exclusive license granted to Veridex by the DLS Agreement through its "use" of Immunicon's Reagents and Instruments in connection with its "Pharma Services" business. Veridex also claims that Immunicon breached its duty of good faith and fair dealing by seeking to "use" and "sell" reagents and instruments covered by the DLS Agreement to potential Veridex customers and therefore prevented Veridex from being able to fulfill its duties under the contract.

The basic question is whether Immunicon's activities in its Pharma Services business are activities that fall within the scope of the exclusive rights that it granted to Veridex under the DLS Agreement. The provisions of the Agreement that are most relevant to that determination are listed here.

- (1) Immunicon granted Veridex the right to be the "exclusive sales, invoicing and collecting agent" and "exclusive instrument and technical service provider for Automated Cell Analysis Systems." § 6.4.1.
- (2) Immunicon also gave Veridex the "world-wide exclusive right under Immunicon Inventions to make, have made; use, sell and have sold Cellular Analysis Products and Automated Cell Analysis Systems within the Field." § 7.2.
- (3) "'Cellular Analysis Product(s)' means products or methods, including without limitation analytical reagents, test kits, consumable products and disposable items, incorporating or utilizing Immunicon Inventions in Cellular Diagnostics." § 2.
- (4) "'Cellular Diagnostics' means (a) the enrichment or isolation of one or more intact cells from body fluids or lymph nodes . . . using magnetic particles in

combination with one or more reagents and (b) analyzing, identifying or quantifying cells or one or more cellular components.” § 2.

- (5) The “Field” means “the human *in vitro* application of Cellular Diagnostics to Cancer and Pre-Cancerous conditions . . . [but does] not include cardiovascular diagnostics and screening, neurological disorder diagnostics, infectious disease diagnostics, hematology, standard blood serum immunoassays for soluble markers and analysis of cells taken by tissue biopsy.” § 2.

Veridex argues that based on a plain reading of these provisions of the Agreement, Immunicon’s Pharma Services business “uses” Immunicon’s products or methods in Cellular Diagnostics to analyze, identify, or quantify cells within the Field, in violation of Veridex’s exclusive rights under the DLS Agreement.

Immunicon interprets these provisions of the DLS Agreement differently. It argues that it does not sell or use any CellSearch Products in connection with its Pharma Services business, and that it does not perform services related to “diagnosis” of cancer or pre-cancerous disease, and therefore its Pharma Services business does not violate the Agreement. It argues that the “Field” is limited only to the “diagnostic” application of Immunicon’s products for “human *in vitro* application,” meaning use by doctors in furtherance of a patient’s health, because that is how “human *in vitro* application of Cellular Diagnostics” would be understood in the industry.

Immunicon further argues that any interpretation of the provisions of the Agreement must be informed by the overall purpose of the Agreement, set forth in § 1.2, which was for the parties to “collaborate to produce products based upon their respective technologies and businesses with the intent that a full range of cellular human cancer diagnostics be developed and manufactured, in part, by Immunicon and in part by [Veridex] and marketed and distributed worldwide by [Veridex].” It follows, Immunicon argues, that because its Pharma Services business is focused on pharmaceutical research, and not on human cancer diagnosis, its business falls outside the



bounds of the Agreement.

Veridex further responds that any reading other than a plain reading of the text would do violence to the Agreement itself, that the defined term "Cellular Diagnostics" is not synonymous with CellSearch, and therefore includes reagents that are not necessarily part of the CellSearch kits; that Immunicon, by performing these "services" that apply Immunicon reagents to blood samples, even for the research purpose of identifying a certain receptor on a CTC for pharmaceutical companies like Pfizer, diminishes the market of customers to whom Veridex would otherwise be able to sell CellSearch Instruments and Reagent kits and therefore, infringes upon Veridex's exclusive rights and breaches Immunicon's duty of good faith and fair dealing. Veridex seeks \$513,426 in damages.<sup>19</sup>

The Agreement in very broad language defines the exclusive rights Immunicon conveyed to Veridex. What seems clear is that what Immunicon does for other pharmaceutical companies involves the use of human blood from which CTCs are extracted through the use of analyzer equipment and to which reagents are applied to isolate certain characteristics on the cancer cells. The Arbitrator concludes that such arrangements infringe upon Veridex's exclusive rights under the Agreement and that it is entitled to an award of damages in the sum of \$304,013, with appropriate interest.<sup>20</sup>

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<sup>19</sup> The amount of damages is principally derived from Respondent's Exhibit 307. This is an internal Immunicon document showing a calculation of the share of income earned by Veridex under the Agreement based upon sales of Immunicon products or services to various pharmaceutical companies for CTC and other testing related to cancer research. The period covered is all of 2005 through the end of the second quarter of 2007. Immunicon does not challenge these calculations although it disputes whether there is any payment due Veridex. It describes Respondent's Exhibit 307 as a "sensitivity analysis" and not an admission of what is owed to Veridex. No Immunicon witness was called to testify with respect to Exhibit 307.

<sup>20</sup> Philip Perez, a Veridex Territory Manager, testified concerning Immunicon having successfully bid to provide CTC analysis for Eli Lilly, a large pharmaceutical company.

It should be understood that this conclusion is limited to the claims made with respect to the Immunicon Pharma Testing Services identified on Respondent's Exhibit 307 dealing with income received and the Veridex share of such income in connection with CTC, IGFR and CEC products or services and does not apply to any other Immunicon activities.

FINAL AWARD

1. The claim by Immunicon that Veridex under the common law or the U.C.C. breached its duty under the Agreement to make reasonable efforts to perform its obligation in the distribution and sale of CellSearch is dismissed with prejudice and Immunicon is awarded no damages.

2. Since there was no fiduciary duty owed by Veridex to Immunicon, Immunicon's claim that it is entitled to an order that Veridex forfeit all sales agency commissions previously credited to it and for an award of punitive damages is dismissed with prejudice.

3. Veridex did not breach the Agreement in connection with Immunicon's request for an audit and such claim is dismissed with prejudice.

4. Veridex on its counterclaim arising out of Immunicon's Pharma Services business is awarded damages in the sum of \$304,013, with interest in accordance with the law of New York.

5. All other claims asserted by the parties are denied and dismissed with prejudice.

6. No costs or fees, including attorneys' fees, are awarded to either party against the other.

7. The administrative fees and expenses of the International Centre for Dispute Resolution ("ICDR") totaling \$54,560.00 shall be borne as incurred by the parties.

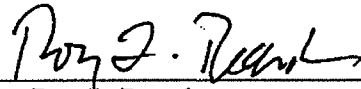
8. The compensation and expenses of the Arbitrator through January 22, 2008, as previously billed by the ICDR, shall be borne equally by the parties. In addition, the remaining compensation and expenses of the Arbitrator in the sum of \$221,911.29 shall be borne equally by the parties.

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Immunicon directly outbid a laboratory in Tennessee which had a relationship with Veridex and had the CellSearch equipment at its laboratory that had been placed there earlier. While this testimony was anecdotal and was based upon hearsay, the incident was not disputed by any Immunicon witness. The Arbitrator does not rely in any way upon this testimony for the conclusion reached on this issue. It is a specific matter which neither party addressed in the post-hearing submissions and is not covered by the damages awarded under the counterclaim.

9. This Final Award is in full settlement of all claims and counterclaims submitted in this arbitration.

Dated: March 3, 2008

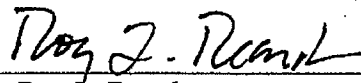


Roy L. Reardon  
Arbitrator

Roy L. Reardon having been designated in accordance with the arbitration agreement entered into between the above-named parties and dated August 17, 2000 and having been duly sworn as Arbitrator, and having duly heard the proofs and allegations of the parties, rendered the above Award.

I hereby certify that, for the purposes of Article 1 of the New York Convention of 1958, on the Recognition and Enforcement of Foreign Arbitral Awards, this Final Award was made in New York, NY.

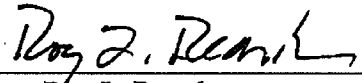
Dated: March 3, 2008



Roy L. Reardon  
Arbitrator

State of New York ) SS:  
County of New York )

I, Roy L. Reardon, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.



Roy L. Reardon  
Arbitrator

**AFFIDAVIT OF SERVICE**

**UNITED STATES DISTRICT COURT  
Southern District of New York**

Index Number: 08 CIV 03188 (RWS)

Date Filed: \_\_\_\_\_

Petitioner:  
In the Matter of the Arbitration Between VERIDEX LLC.

vs.

Respondent:  
IMMUNICON CORPORATION,

For:  
Patterson, Belknap, Webb & Tyler LLP  
1133 Avenue Of The Americas  
21st Floor  
New York, NY 10036-6710

Received these papers to be served on IMMUNICON CORPORATION located at 3401 Masons Mill Road, Suite 100, Huntingdon Valley, Pa. 19006.

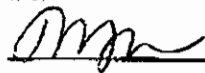
I, Eric M. Afflerbach, being duly sworn, depose and say that on the 4th day of April, 2008 at 11:25 am, I:

Served the above named Entity by delivering a true copy of the Notice of Petition to Confirm Arbitration Award With Annexed Petition, Civil Cover Sheet, Rule 7.1 Statement, Individual Practices of Judge Robert W. Sweet, Individual Practices of Magistrate Judge Eaton, ECF Procedures/Instructions to Joseph Aceto, Attorney, as authorized to accept on behalf of the above named Entity.

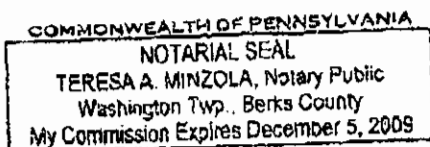
Description of Person Served: Age: 55, Sex: M, Race/Skin Color: White, Height: 5'9", Weight: 200, Hair: Gray, Glasses: N

I am over the age of 18, am not a party in the above action, and am a Certified Process Server, in good standing, in the jurisdiction in which the process was served.

Subscribed and sworn to before me on the 8th day of April, 2008 by the affiant who is personally known to me.



Eric M. Afflerbach  
Process Server



Our Job Serial Number: 2008001393  
Ref: 08 Civ 3188